AUTOBAHN™

Tibial Nailing System

SURGICAL TECHNIQUE GUIDE

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Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

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SURGICAL TECHNIQUE GUIDE

AUTOBAHN™

Tibial Nailing System

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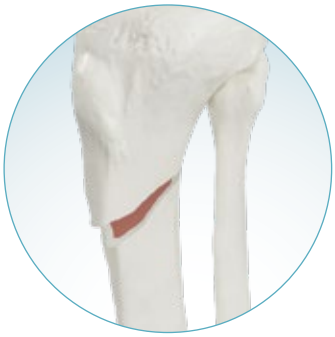
Tibial Nailing System

The AUTOBAHN™ Tibial Nailing System is a comprehensive system that incorporates both infrapatellar and suprapatellar approaches in a single tray. The system provides multiple fixation options to address a variety of tibia fractures.

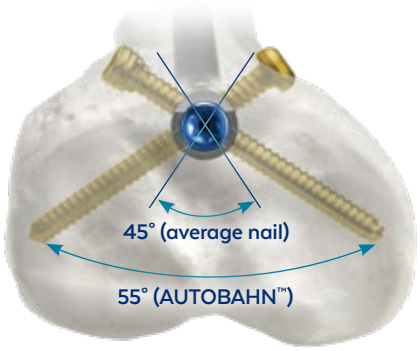
Threaded Anterior Oblique Locking Holes

Allow for lagging of anterior fracture fragments



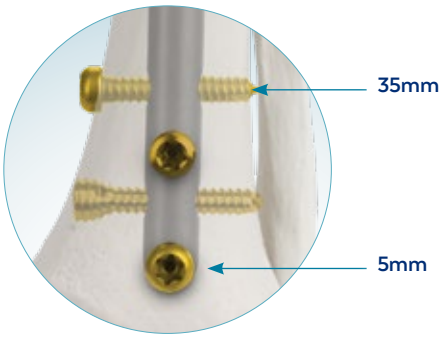
Unique 55° Proximal Oblique Screws

Accommodate the natural anatomy of the tibia to reduce screw prominence around the tibial tuberosity



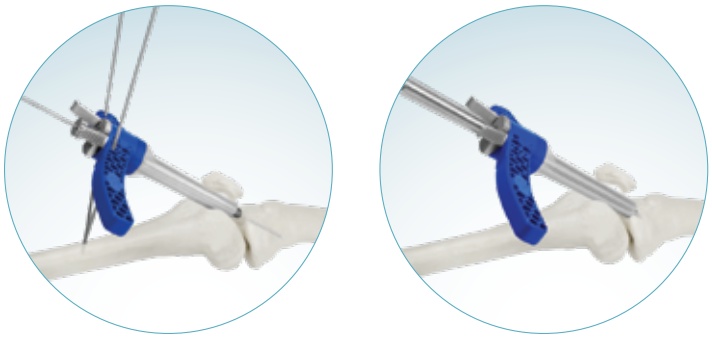
Distal Locking Options

- SureStart™ threaded locking featured in all 4 distal locking holes allows for optimal fixation in distal patterns
- Most distal hole is 5mm from the distal end of the nail for extreme nailing cases
- Most proximal hole is 35mm from the distal end of nail



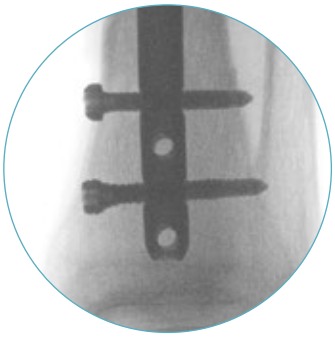
Suprapatellar Cannula

- One-piece soft Suprapatellar Cannula reduces intraoperative assembly and is designed to protect the articular surface
- Provides multiple pin anchoring options to the femur and tibia



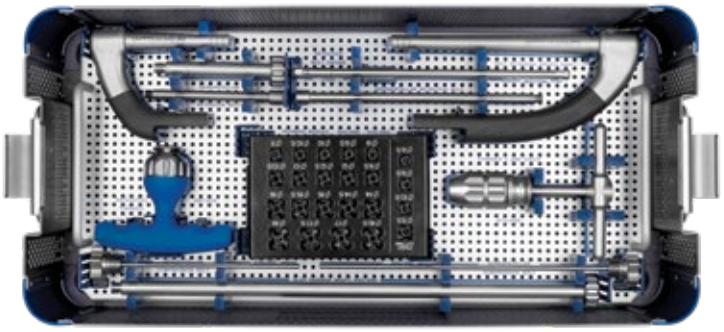
Headless Locking Screws

Designed to reduce soft tissue irritation



Comprehensive Instrument Set

Includes instruments for suprapatellar and infrapatellar approaches



Radiolucent Aiming Guide

- Designed for accuracy and clarity
- Optimized anterior distance for percutaneous screw insertion

Self-Retaining Drill Sleeve

- Easy, automatic retention during proximal locking screw drilling and insertion
- Avoids targeter deflection during screw insertion

Compression Bolt

- Instrument-based compression retains functionality of all holes in the nail

Locking screw in dynamic slot

Locking screw in compression mode

IMPLANT OVERVIEW

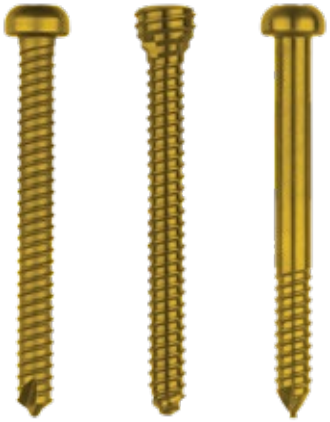
Tibial Nail

- Designed to treat a variety of tibial shaft fractures and help reduce soft tissue irritation
- 10° Herzog Bend
  - Located 67mm from the proximal end of the nail for optimal fit

Locking Screws*

- Headless screws to help reduce tissue irritation
- Standard and headless locking screws
  - 4.0mm screws for 8mm and 9mm tibial nails
  - 5.0mm screws for 10mm to 15mm tibial nails
- Partially threaded locking screws are available for dynamic compression

** Locking screws are additionally available in CoCr*



End Caps

- Compress the most proximal oblique screw to create a fixed angle construct
- Optional cap to prevent tissue ingrowth into the proximal end of the nail

SURGICAL TECHNIQUE

AUTOBAHN™ Tibial Nailing System

Suprapatellar Approach

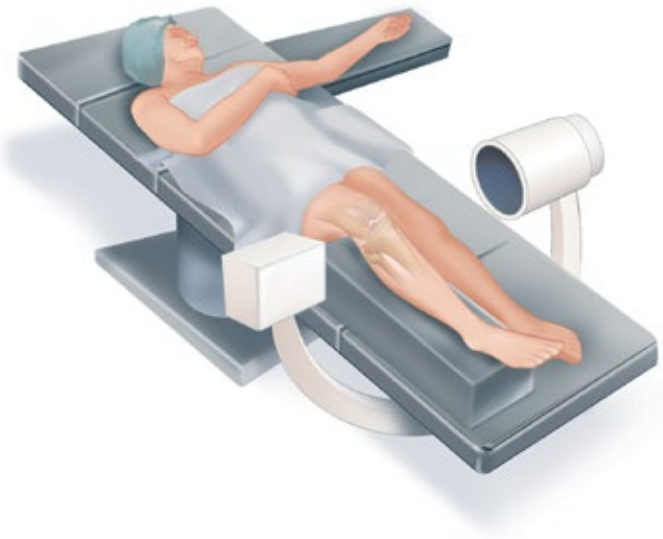
Refer to the package insert (also printed in the back of this manual) for important information on indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

STEP 1 PREOPERATIVE PLANNING

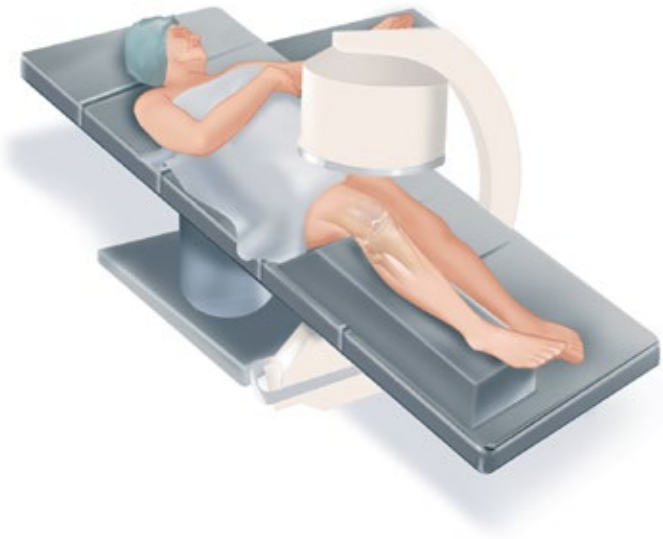
Use the nail length and diameter ruler to estimate the appropriate nail needed for the medullary canal. Place the ruler flush against the uninjured tibia. Use the C-arm to confirm nail length and diameter.

STEP 2 PATIENT POSITIONING

The patient is placed under anesthesia and positioned supine on a radiolucent table with the operative leg in the semi-extended position, which allows for AP and lateral views without moving the operative leg.



Lateral view



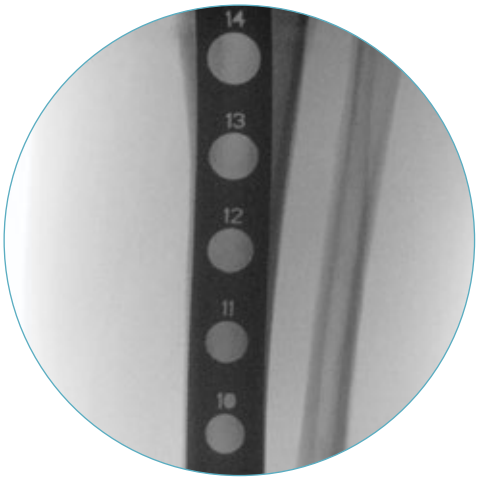
AP view

STEP 3 FRACTURE REDUCTION

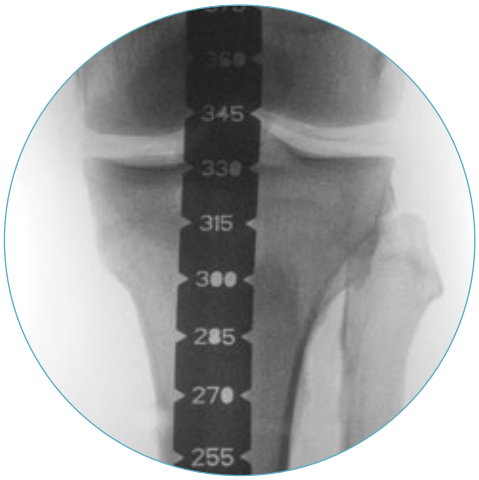
Fracture reduction is necessary to re-establish anatomic length, alignment, and rotation of the tibia. Direct reduction instruments and small fragment plates are available to help achieve reduction.

STEP 4 DETERMINE LENGTH AND DIAMETER

Use the **Radiographic Nail Length and Diameter Gauge** to determine nail length and diameter. Measure the diameter of the intramedullary canal at the narrowest point. Determine the nail length where the gauge aligns with the physeal scar or the desired nail insertion depth. Length may also be determined by reading the measurement on the K-wire.



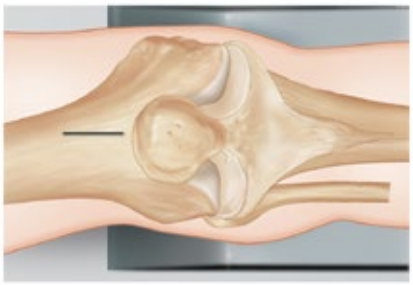
Diameter measurement



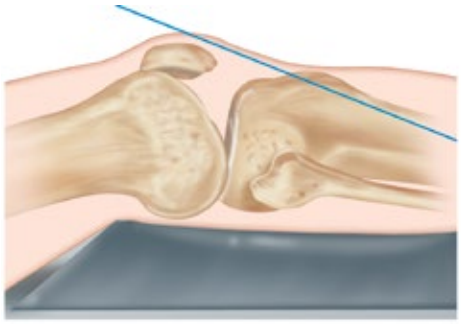
Length measurement

STEP 5 INCISION AND ENTRY POINT

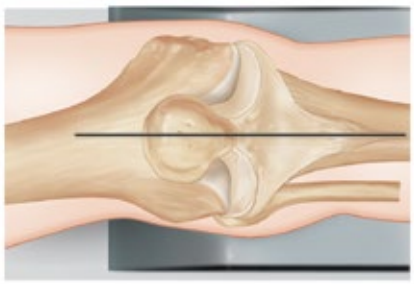
With the knee extended, create a longitudinal incision superior to the patella. Expose the quadriceps tendon by blunt dissection and longitudinally split the tendon at its midline. Ensure that there is enough space for the Suprapatellar Cannula to fit under the patella. The entry point is shown below in different views.



Longitudinal incision



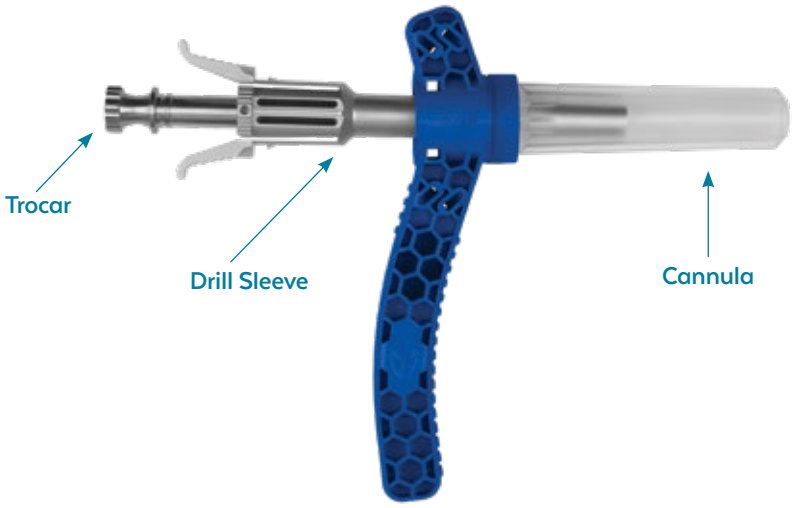
Ventral edge of tibial plateau



Axis of medullary canal

Cannula Assembly

Connect the **Suprapatellar Cannula**, **Suprapatellar Drill Sleeve**, and the **Suprapatellar Trocar** to form the Suprapatellar Cannula assembly.

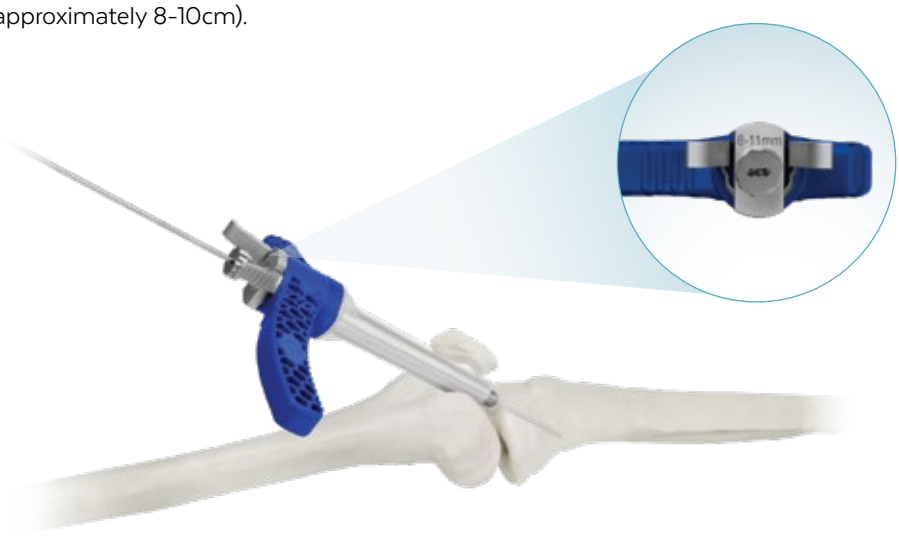


Suprapatellar Cannula Assembly

K-wire Insertion

Insert the Suprapatellar Cannula assembly into the incision until it reaches the entry point in the proximal tibia.

Insert **3.2x450mm Threaded Tip K-wires** through the Trocar, manually or under power, into the proximal tibia. Insert K-wires to the desired depth (approximately 8-10cm).



Anchor the Suprapatellar Cannula into the proximal tibia or distal femur using 3.2x450mm Threaded Tip K-wires. Confirm K-wire position using AP and lateral fluoroscopy.

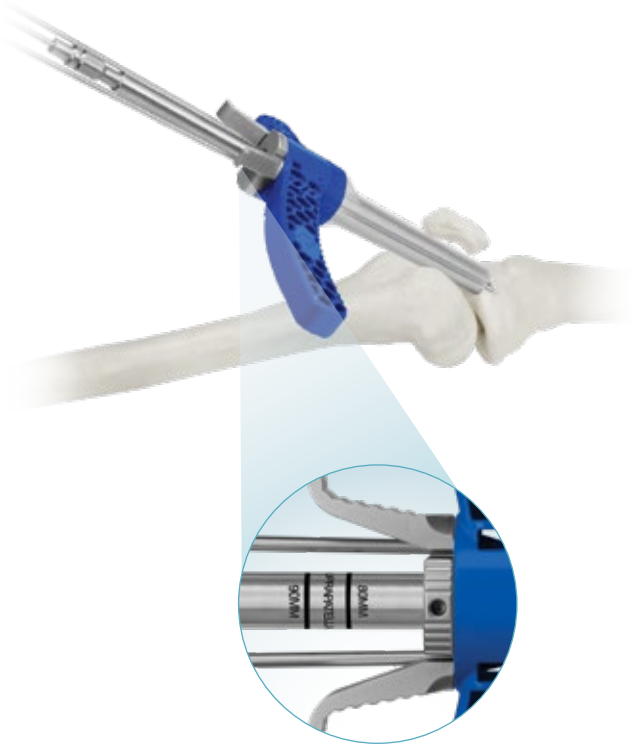
Femoral pin fixation option

Tibial pin fixation option

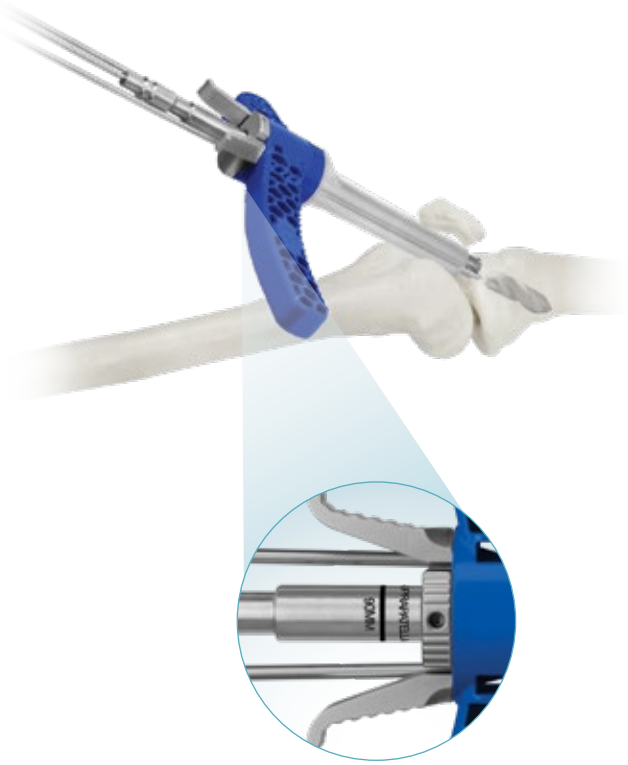
STEP 6 ENTRY REAMING

Remove the Suprapatellar Trocar and advance the Cannula and Drill Sleeve to the entry point in the proximal tibia. Using the **12mm Cannulated Entry Drill**, drill over the K-wire through the Drill Sleeve until it reaches the entry point in the proximal tibia. Open the medullary canal using the 12mm Cannulated Entry Drill and drill through the Drill Sleeve to the desired depth (approximately 8-10cm). Do not contact the posterior cortex. Note the markings on the drill for suggested depths.

Confirm position and trajectory using fluoroscopy in AP and lateral views. Remove the K-wire and drill.



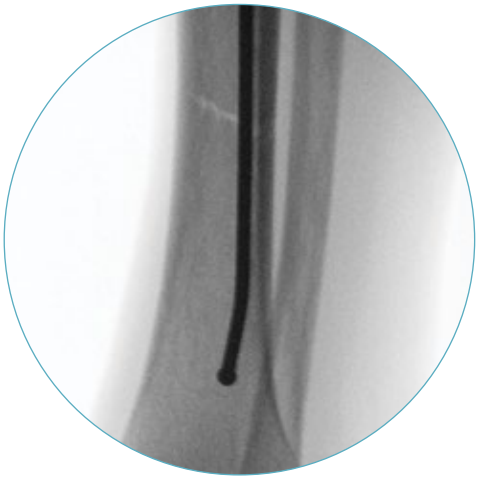
12mm Cannulated
Entry Drill insertion



12mm Cannulated
Entry Drill final position

Ball-Tip K-wire Insertion

Manually insert the **3x1000mm Ball-Tip K-wire** through the Cannula and Drill Sleeve into the center of the canal. Advance the K-wire past the fracture line toward the distal tibia. Using fluoroscopy, confirm the K-wire is centered.



Ball-Tip K-wire passing fracture line

STEP 7 REAM CANAL

Confirm cannula position before reaming.

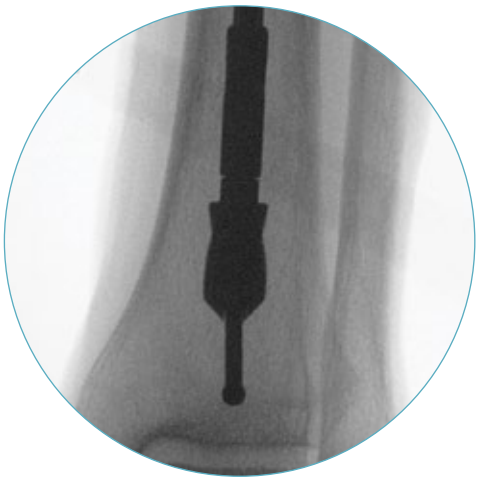
Use fluoroscopy to confirm fracture reduction. Ensure the 3mm Ball-Tip K-wire is in the canal at the desired depth.

Through the Suprapatellar Cannula and Suprapatellar Drill Sleeve, use the selected reamer to ream in 0.5mm increments, under power applying steady pressure. Partially retract the reamer to clear debris from the canal while maintaining power. Ream to 0.5-1.5mm greater than the selected nail diameter.

If necessary, the **Reamer Extension** or **620mm Flexible Reamer Shaft** may be used for the suprapatellar approach.

Remove the reamer and the Suprapatellar Drill Sleeve.

Remove the Reamer Shaft, leaving the Ball-Tip K-wire in place for a later step.

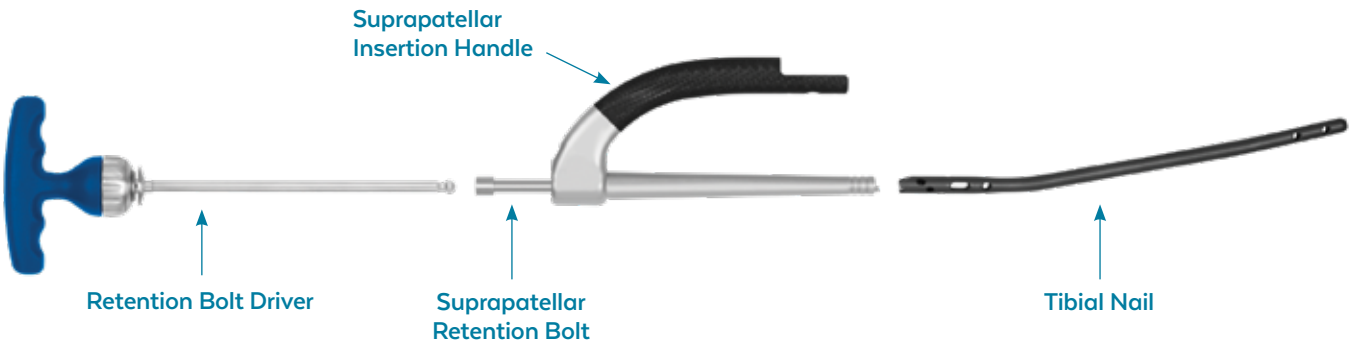


Reamer advancement over Ball-Tip K-wire

STEP 8 NAIL ATTACHMENT

Connect the **Suprapatellar Insertion Handle** and **Suprapatellar Retention Bolt** to the proximal end of the nail using the **Retention Bolt Driver**.

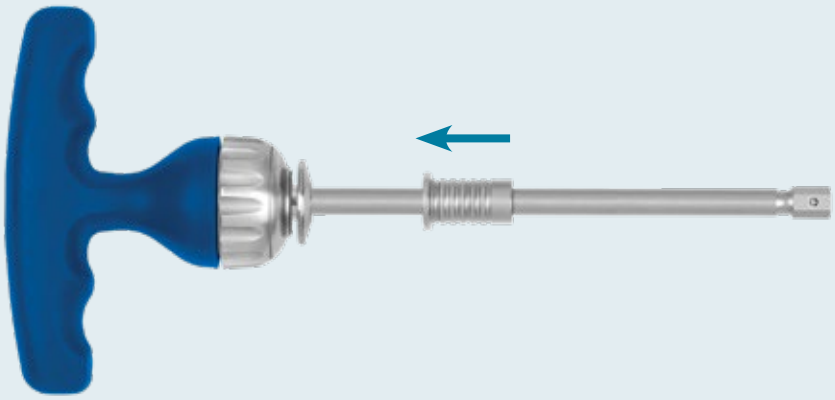
Confirm secure connection of nail to handle.



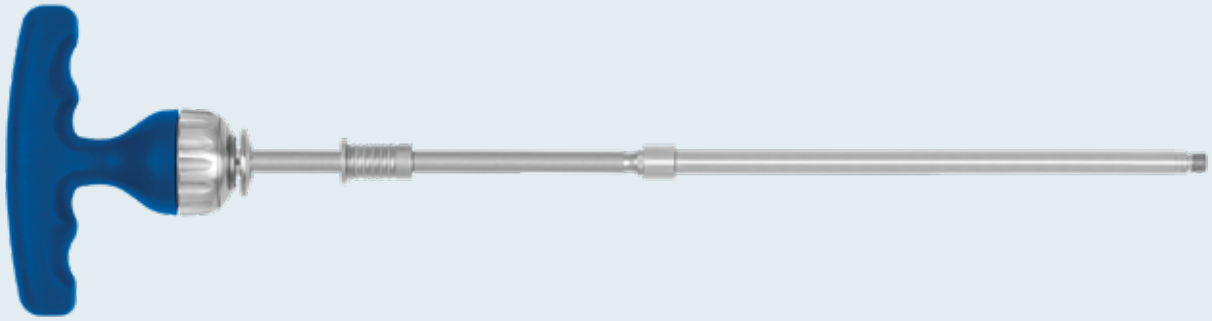
8MM SELF-RETAINING DRIVER SHAFT

The 8mm Self-Retaining Driver Shaft may be used instead of the Retention Bolt Driver to connect the Retention Bolt to the nail.

Pull back the retention sleeve on the driver shaft.



Insert the driver shaft into the hex of the Retention Bolt to release retention.



STEP 9 NAIL INSERTION

Ensure that the Retention Bolt is tightened when inserting the nail.

Insert the nail assembly over the K-wire through the Suprapatellar Cannula until the desired depth is reached. Attach the **Impactor** to the Suprapatellar Insertion Handle to assist with nail insertion. Impact using the **Slotted Mallet**. Avoid impacting the carbon fiber portion of the insertion handle directly.

Use fluoroscopy to confirm proximal nail location.

Remove the 3mm Ball-Tip K-wire.

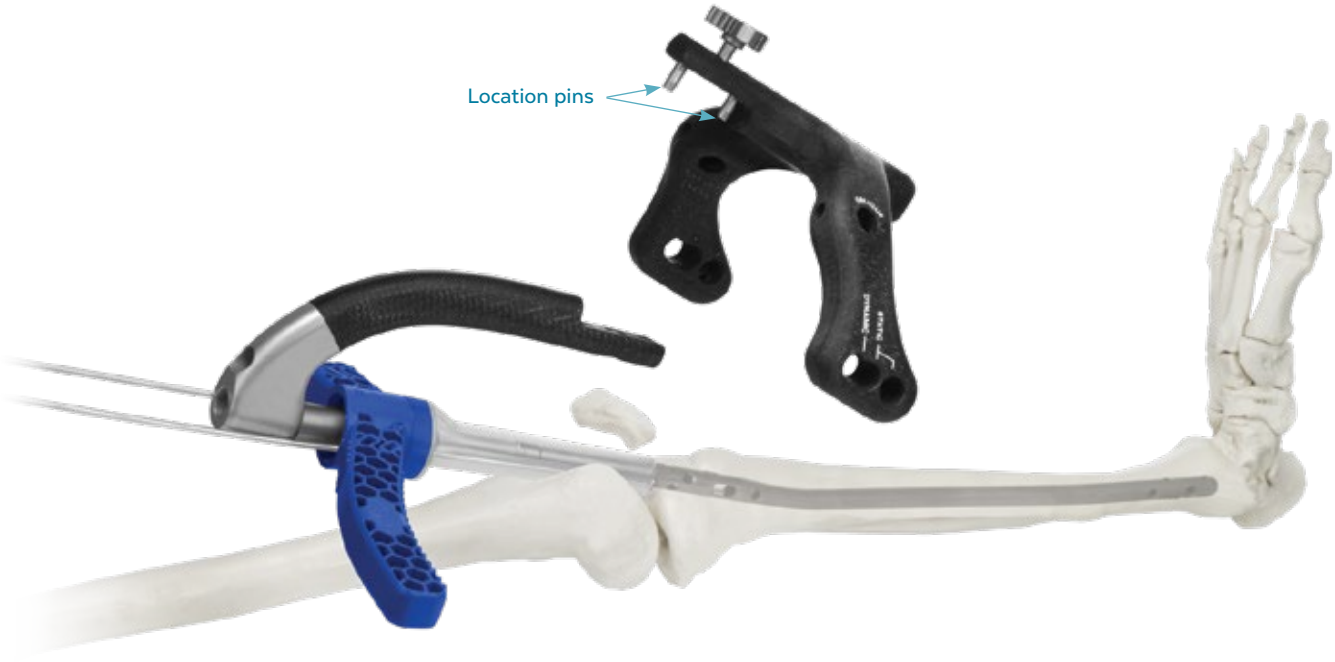
If fracture compression using the dynamic locking screw slot is desired, the nail must be over-inserted a safe distance from the entry point to accommodate 7mm of maximum compression.

Nail insertion with Impactor

Nail fully seated

STEP 10 PROXIMAL AIMING GUIDE ASSEMBLY

Attach the **Proximal Aiming Guide** to the Suprapatellar Insertion Handle by connecting the location pins onto the Insertion Handle. Ensure that the Aiming Guide is fully seated and secured. Rotate the thumb screw clockwise until the Aiming Guide Insertion Handle assembly is rigid.



Attaching the Proximal Aiming Guide

Fully assembled

STEP 11 COMPRESSION

To compress the fracture up to 7mm, use the compression slot at the proximal end of the nail. Insert the **Soft Tissue Sleeve**, appropriate drill sleeve, and Trocar into the dynamic position in the Proximal Aiming Guide after locking distally.

Create a stab incision at the intersection of the Soft Tissue Sleeve and skin surface. Advance the Soft Tissue Sleeve until it reaches bone. Drill through both cortices of the bone using the selected drill and drill sleeve. Remove the drill sleeve.

Drill Size	Nail Diameter	Locking Screws
3.3mm	8 and 9mm Nails	4mm Locking Screws
4.2mm	10-15mm Nails	5mm Locking Screws

Creating a stab incision

Drilling through cortices

COMPRESSION (CONT'D)

Insert a locking screw into the dynamic position of the nail through the Soft Tissue Sleeve. Using the **Suprapatellar Compression Bolt**, compress the locking screw in the static position until the desired compression is achieved.

Insert a second proximal locking screw into the most distal static hole of the proximal locking options to lock in the compression. Remove the Compression Bolt before inserting oblique screws.

Locking screw in dynamic slot

Locking screw in compression mode

Alternatively, attach the Impactor and **Slap Hammer Shaft** to use the backslap technique.

If necessary, over-insert the nail to avoid nail prominence after compression.

Backslap technique

STEP 11 PROXIMAL LOCKING SCREW INSERTION

Insert Trocar Assembly

Insert the three-part Trocar assembly (Soft Tissue Sleeve, Drill Sleeve, and Trocar) through the desired proximal hole in the Proximal Aiming Guide.

Ensure that the correct drill sleeve and Trocar combination are chosen for the corresponding nail.

Drill Size	Nail Diameter	Locking Screws
3.3mm	8 and 9mm Nails	4mm Locking Screws
4.2mm	10-15mm Nails	5mm Locking Screws

Drill and Determine Length

Ensure that the drill sleeve is securely placed. Use the drill corresponding to the screw size as shown in the table above. Drill through both cortices until the tip penetrates the far cortex.

Confirm drill bit position using fluoroscopy. Determine the length from the calibrated drill bit and select the corresponding locking screw. Remove the drill and drill sleeve. Alternatively, the depth gauge may be used to determine screw length.

Length calibration

PROXIMAL LOCKING SCREW INSERTION (CONT'D)

Insert Locking Screw

Assemble the Locking Screw Driver by inserting the Retention Rod until it snaps into place.

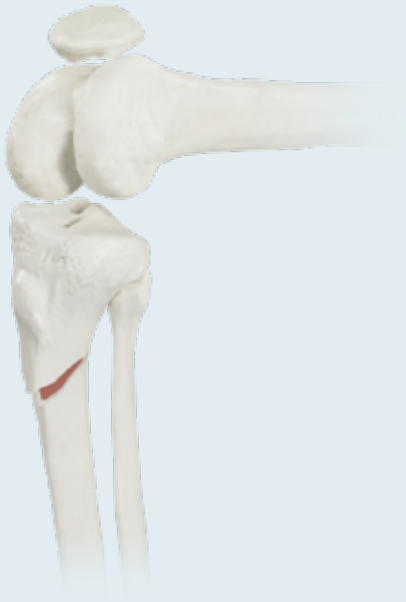
Select the appropriate locking screw. Using the Retention Rod, secure the locking screw to the Locking Screw Driver. Insert the locking screw through the Soft Tissue Sleeve, manually or under power.

Confirm placement using fluoroscopy.

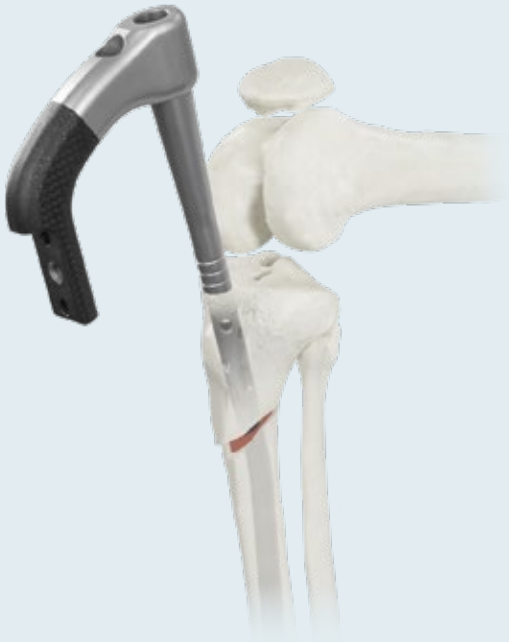
Repeat steps for additional proximal holes as necessary.

THREADED ANTERIOR OBLIQUE HOLE

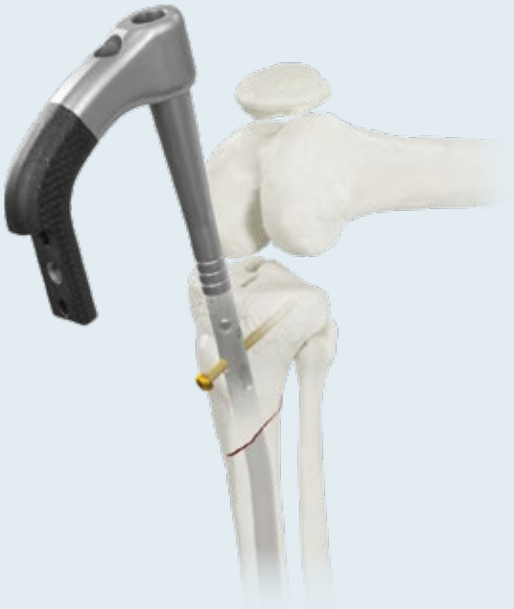
The threaded anterior oblique hole allows lagging through the nail to help reduce apex anterior deformity. The threaded feature in the nail is designed for fracture reduction.



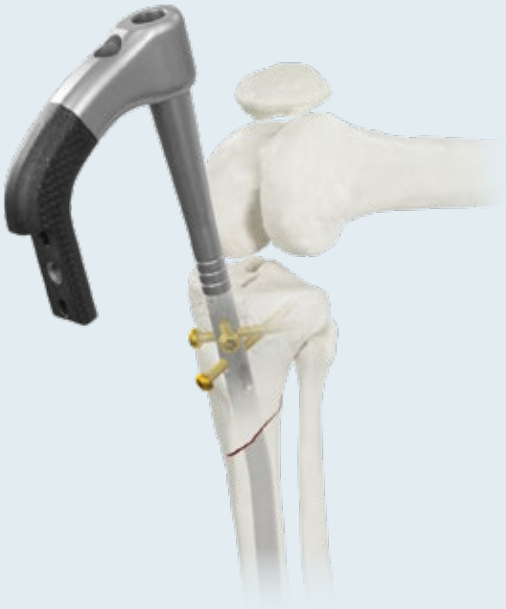
Proximal third fracture



Nail insertion



Fracture reduction



Final construct

HEADLESS LOCKING SCREWS

Headless screws are designed to decrease screw head prominence and reduce soft tissue irritation in the proximal and distal medial tibia.

Headless screws can be used instead of standard locking screws with any locking options in the AUTOBAHN™ Tibial Nailing System. They should only be placed in metaphyseal bone.

Headless Screw Insertion

Drill and determine length as described in Step 11.

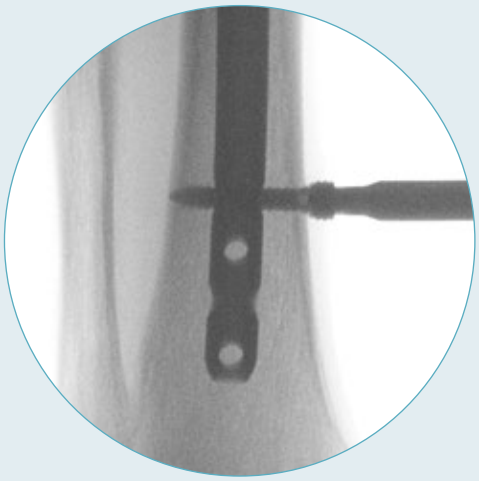
Attach the headless locking screw to the Locking Screw Driver using the self-retaining feature or the threaded capture mechanism.

Using fluoroscopy, insert the headless locking screw until the head of the screw is flush with the bone.

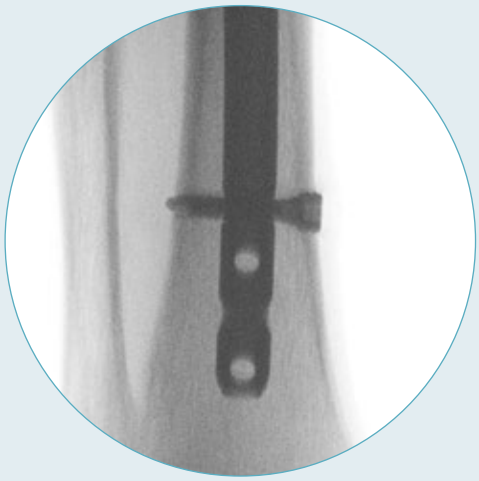
Verify screw length using fluoroscopy.

Repeat for additional proximal holes as necessary.

A countersink tool is available.



Headless Locking Screw insertion with driver



Headless Locking Screw fully inserted

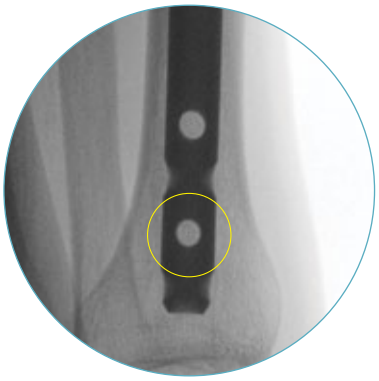
STEP 13 DISTAL LOCKING SCREW INSERTION

Alignment

Use the appropriate locking screws and drill bit for the selected diameter nail.

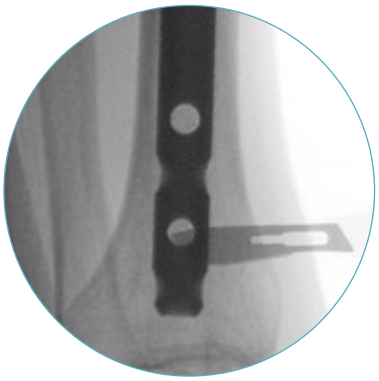
If using the backslap technique or Compression Bolt, distal locking must be performed before proximal locking.

Using fluoroscopy, confirm fracture reduction prior to distal locking. Align the C-arm with the distal hole until a perfect circle is formed.



Determine Incision Point

Determine the incision point using fluoroscopy.

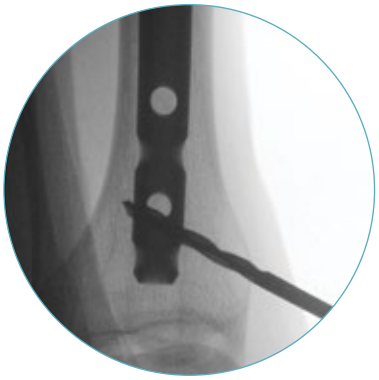


Drill and Determine Length

Insert the appropriate drill tip in the center of the locking hole. Confirm position using fluoroscopy. The drill should almost completely fill the hole. Hold the drill in this position and drill through both cortices.

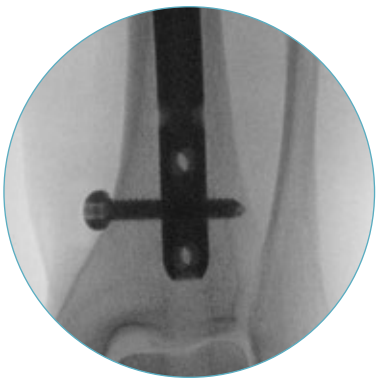
Remove the drill and insert the Locking Screw Length Gauge through the pre-drilled hole. Rest the gauge on the near cortical wall, extend the tip completely through the tibia, and retract until it reaches the far cortical wall.

Determine the screw length by reading the measurement on the gauge.



Insert Locking Screw

Insert the appropriate length locking screw using the Locking Screw Driver manually or under power. Verify screw length using fluoroscopy. Insert up to four locking screws following the steps above.



DISTAL LOCKING SCREW INSERTION (CONT'D)

Removing Instruments

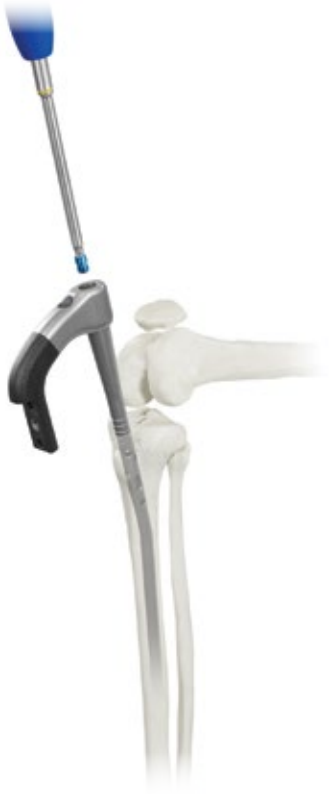
Loosen the Retention Bolt with the Retention Bolt Driver. Remove the Insertion Handle and Aiming Guide assembly together.

Detach the Aiming Guide by rotating the thumbwheel counterclockwise.

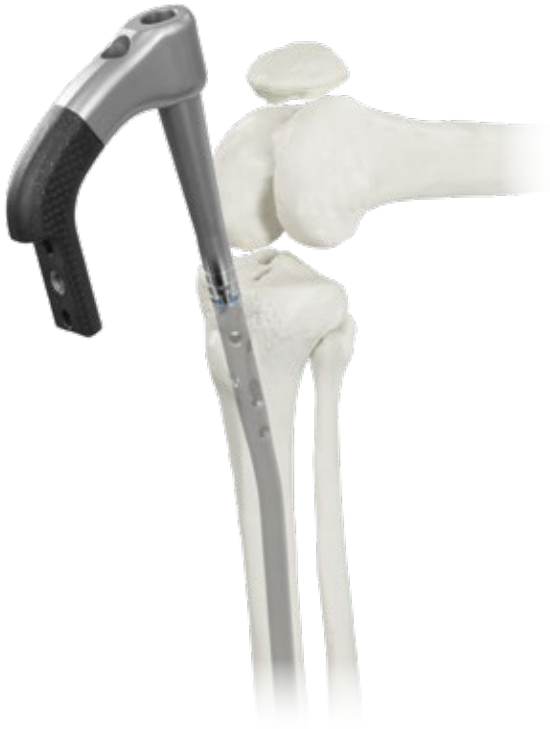
OPTIONAL: END CAP INSERTION

Once the nail is in position, remove the Suprapatellar Insertion Handle by unthreading the Retention Bolt using the Retention Bolt Driver. Alternatively, remove the Retention Bolt, as the Suprapatellar Insertion Handle can be used to align the end cap to the top of the nail.

Optional end caps are available to prevent bony ingrowth or to extend the nail length. The end cap engages the most proximal oblique locking screw to create a fixed-angle construct. Use a 1.8mm K-wire to assist with end cap insertion if desired. Attach the end cap to the **Long Locking Screw Driver** and insert into the top of the nail. Confirm nail position using fluoroscopy.



End cap insertion



End cap fully seated

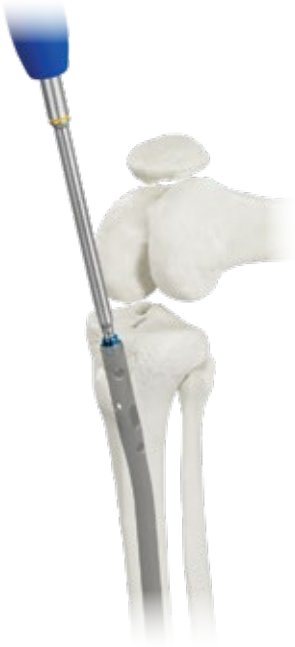
OPTIONAL: NAIL REMOVAL

Remove the nail through an infrapatellar incision.

Clear the end cap and the locking implants of any tissue ingrowth. Remove the end cap using the Long Locking Screw Driver. Remove all locking screws except one proximal locking screw using the Locking Screw Driver.

Before removing the final locking screw, thread the **Extraction Bolt** into the nail and tighten to prevent rotation or displacement of the nail posteriorly below the tibial plateau. Attach the Slap Hammer Shaft to the Extraction Screw. Remove the remaining locking screw using the Locking Screw Driver.

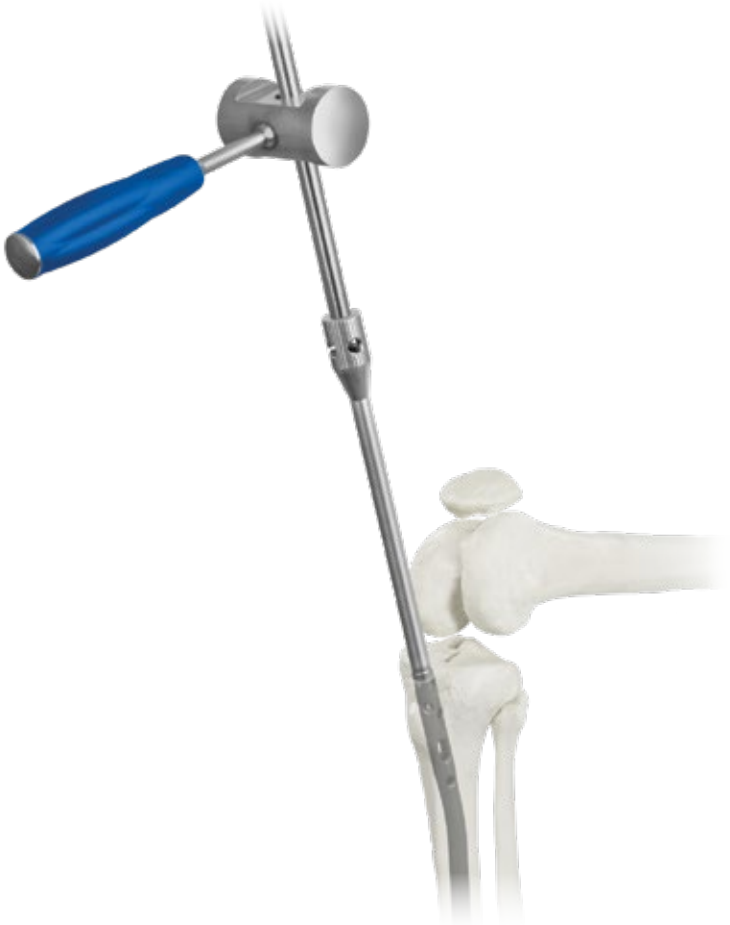
Gently impact to extract the nail using the Slotted Mallet.



End cap removal

Extraction Bolt insertion

Slap Hammer Shaft attachment



Nail removal

SURGICAL TECHNIQUE

AUTOBAHN™ Tibial Nailing System

Infrapatellar Approach

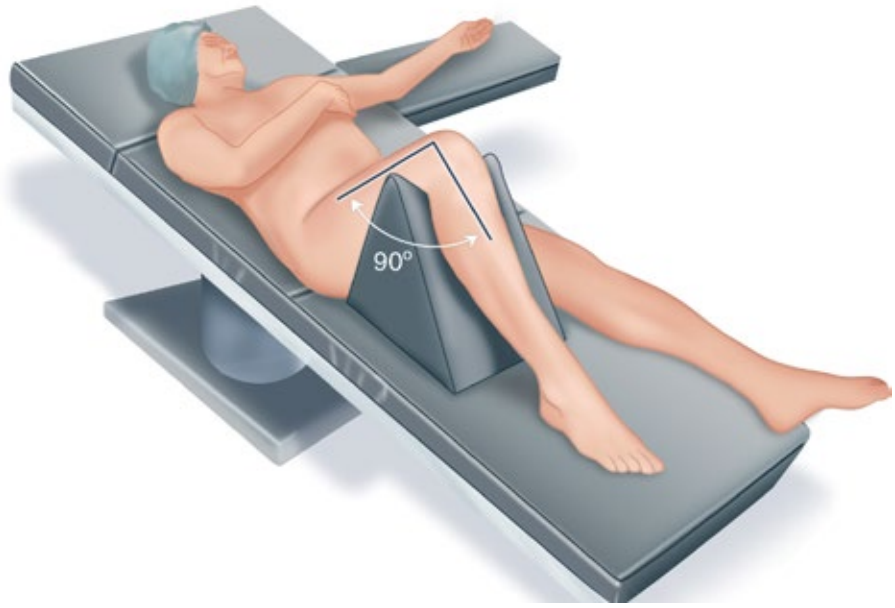
STEP 1 PREOPERATIVE PLANNING

Use the nail length and diameter ruler to estimate the appropriate nail needed for the medullary canal. Place the ruler flush against the uninjured tibia. Use the C-arm to confirm nail length and diameter.

STEP 2 PATIENT POSITIONING

Place the patient under anesthesia and position supine on the radiolucent table with the injured leg flexed at 90°. If necessary, use a bump to allow for fracture reduction and stabilization.

Position the C-arm so the tibia is visualized in the AP and lateral views.

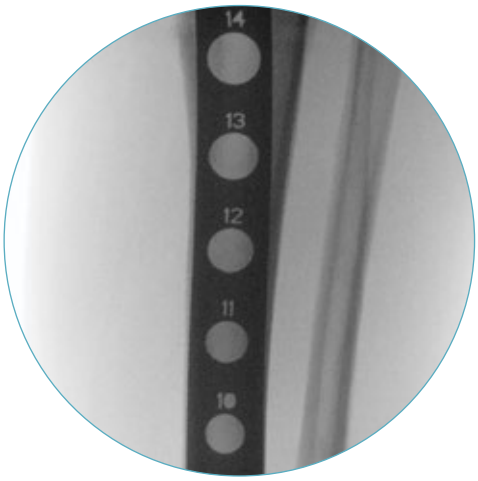


STEP 3 FRACTURE REDUCTION

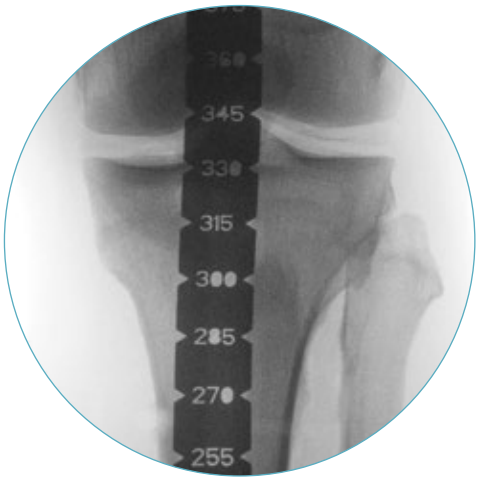
Fracture reduction is necessary to re-establish anatomic length, alignment, and rotation of the tibia. Direct reduction instruments and small fragment plates are available to help achieve reduction.

STEP 4 DETERMINE LENGTH AND DIAMETER

Using the Radiographic Nail Length and Diameter Gauge to determine nail length and diameter. Measure the diameter of the intramedullary canal at the narrowest point. Determine the nail length where the gauge aligns with physeal scar or the desired nail insertion depth. Length may also be determined by reading the measurement on the K-wire.



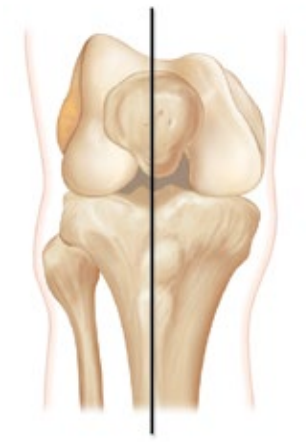
Diameter measurement



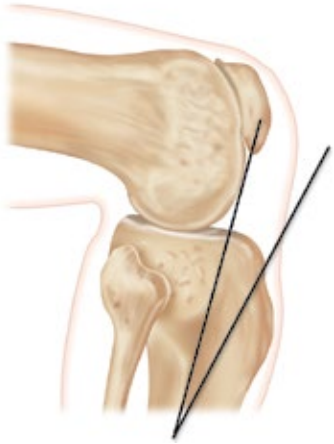
Length measurement

STEP 5 INCISION AND ENTRY POINT

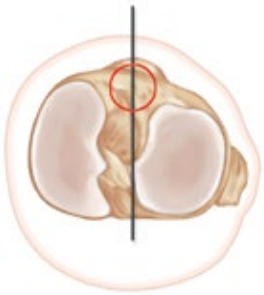
Create an incision in line with the central axis of the tibial canal starting at the inferior pole of the patella and extending to the tibial tuberosity. The entry point is shown below in different views.



Axis of intramedullary canal



Ventral edge of tibial plateau

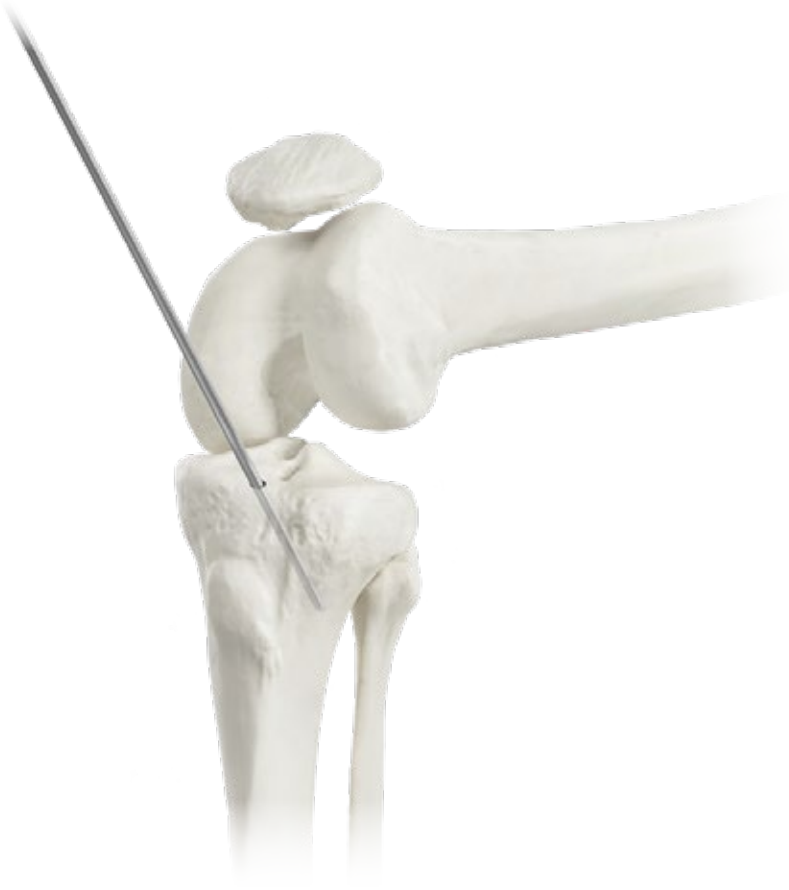


Intercondylar eminence

K-wire Insertion

Insert the 3.2mm Threaded Tip K-wire, manually or under power, into the proximal tibia to the desired depth (approximately 8-10cm).

Confirm K-wire position using fluoroscopy in AP and lateral views.



K-wire insertion

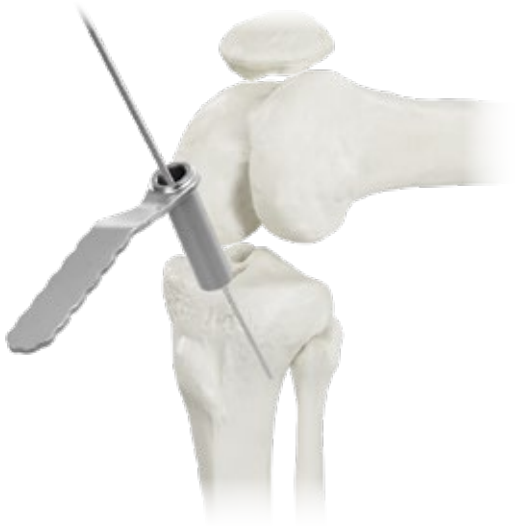
STEP 6 ENTRY REAMING

Place the **12mm Infrapatellar Drill Sleeve** over the K-wire until it reaches the entry point in the proximal tibia. Open the proximal tibia using the 12mm Cannulated Entry Drill and drill through the drill sleeve to the desired depth (approximately 8-10cm). Do not contact the posterior cortex. Note the markings on the drill for suggested depths.

Confirm position and trajectory using fluoroscopy in AP and lateral views. Remove the K-wire, drill, and drill sleeve.

Alternatively, place the **Cannulated Awl** over the K-wire through the 12mm Infrapatellar Drill Sleeve and open the medullary canal. Rotate to advance the awl to the desired depth (approximately 8-10cm). Remove the K-wire, awl, and drill sleeve.

12mm Drill Sleeve

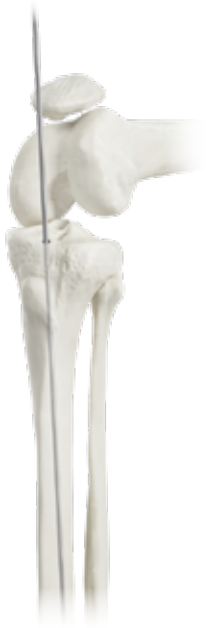


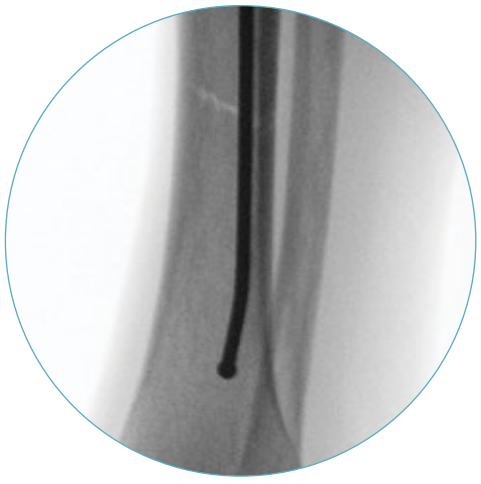
Entry drilling

Proximal tibia entry point

Ball-Tip K-wire Insertion

Manually insert the 3x1000mm Ball-Tip K-wire into the center of the canal. Advance the K-wire past the fracture line toward the distal tibia to desired nail depth. Using fluoroscopy, confirm the K-wire is centered.



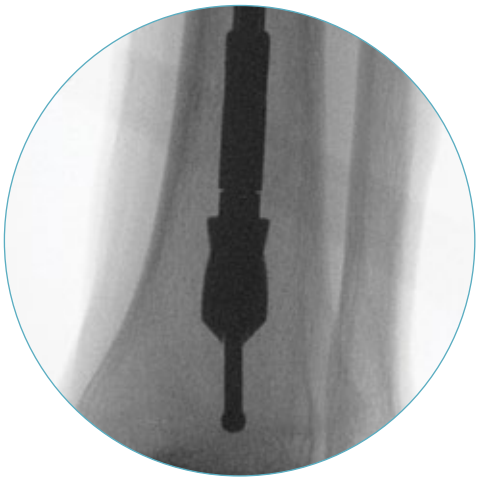


Insert Ball-Tip K-wire

STEP 7 REAM CANAL

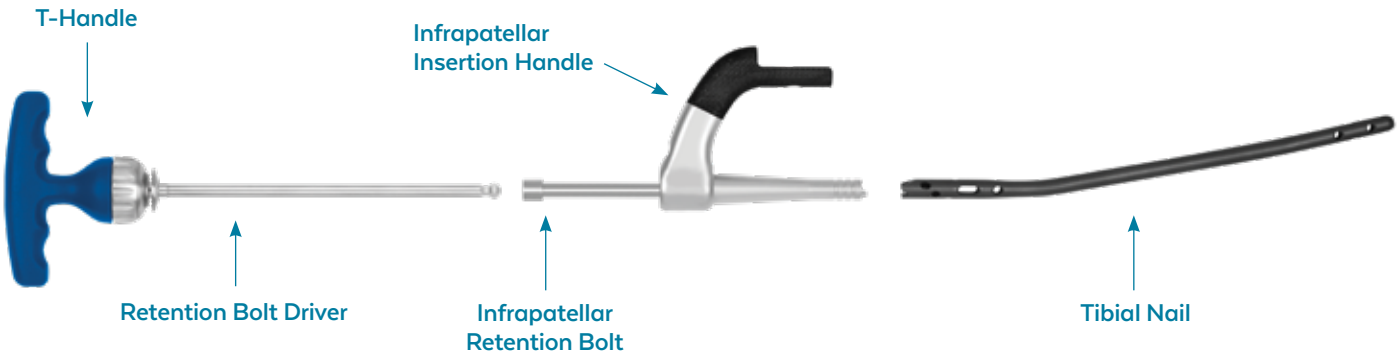
With the selected reamer, ream in 0.5mm increments under power applying steady pressure. Partially retract the reamer to clear debris from the canal while maintaining power. Ream to 0.5-1.5mm greater than the selected nail diameter.

Remove the Reamer Shaft and leave the Ball-Tip K-wire in place for a later step.



STEP 8 NAIL ATTACHMENT

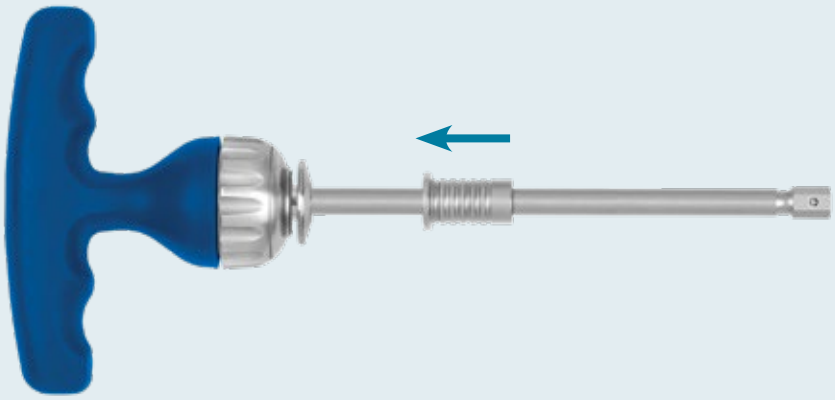
Connect the **Infrapatellar Insertion Handle** and **Tibial Nail Infrapatellar Retention Bolt** to the proximal end of the nail using the Retention Bolt Driver.



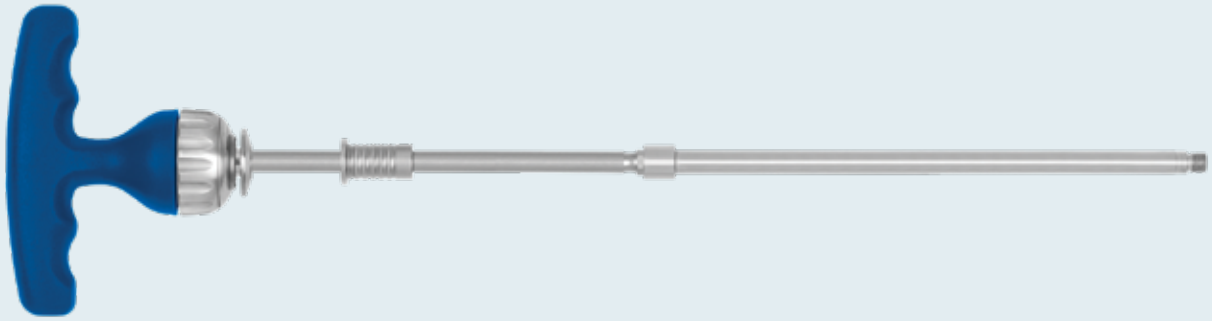
8MM SELF-RETAINING DRIVER SHAFT

The 8mm Self-Retaining Driver Shaft may be used instead of the Retention Bolt Driver to connect the Retention Bolt to the nail.

Pull back the retention sleeve on the driver shaft.



Insert the driver shaft into the hex of the Retention Bolt to release retention.



STEP 9 NAIL INSERTION

Ensure that the Retention Bolt is tightened when inserting the nail.

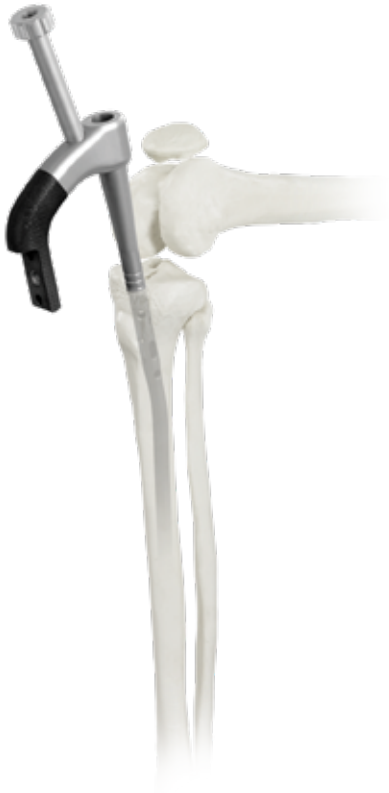
Insert the nail assembly into the intramedullary canal by rotating and advancing it until it is at or below the tibial opening. Attach the Impactor to the Infrapatellar Insertion Handle. Impact using the Impactor or use the Slap Hammer Shaft with the Slotted Mallet. Avoid impacting the carbon fiber portion of the insertion handle directly.

Use fluoroscopy to confirm proximal nail location.

Remove the 3mm Ball-Tip K-wire.

If fracture compression using the dynamic locking screw slot is desired, the nail must be over-inserted a safe distance from the entry point to accommodate 7mm of maximum compression.

Nail insertion with Impactor

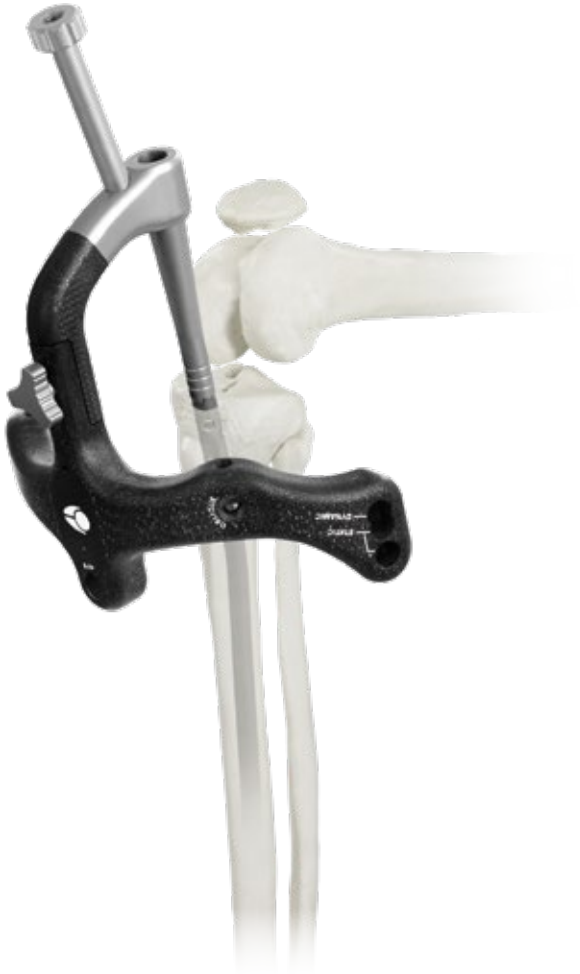


Nail fully seated

STEP 10 PROXIMAL AIMING GUIDE ASSEMBLY

Attach the Proximal Aiming Guide to the Infrapatellar Insertion Handle by connecting the location pins onto the Insertion Handle. Ensure that the Aiming Guide is fully seated and secured. Rotate the thumb screw clockwise until the Aiming Guide assembly is rigid.

Attaching Proximal Aiming Guide



Fully assembled

STEP 11 COMPRESSION

To compress fractures up to 7mm, use the compression slot at the proximal end of the nail. Insert the Soft Tissue Sleeve, the appropriate drill sleeve, and the Trocar into the dynamic position in the Proximal Aiming Guide after locking distally.

Create a stab incision at the intersection of the Soft Tissue Sleeve and skin surface. Advance the Soft Tissue Sleeve until it reaches bone. Drill through both cortices of the bone using the selected drill and drill sleeve. Remove the drill sleeve.

Drill Size	Nail Diameter	Locking Screws
3.3mm	8 and 9mm Nails	4mm Locking Screws
4.2mm	10-15mm Nails	5mm Locking Screws

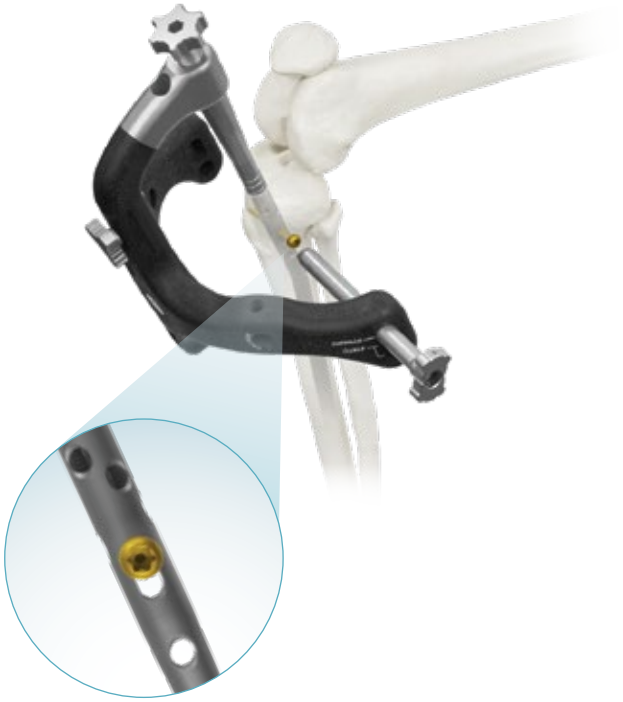
Creating a stab incision

Drilling through cortices

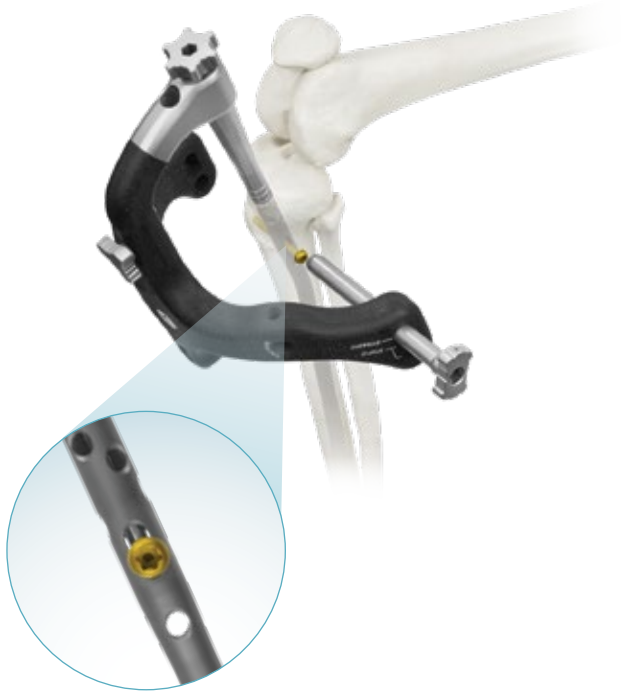
Insert a locking screw into the dynamic position of the nail through the Soft Tissue Sleeve. Using the **Infrapatellar Compression Bolt**, compress the locking screw in the static position until the desired compression is achieved.

Insert a second proximal locking screw into the most distal static hole of the proximal locking options to lock in the compression. Remove the Infrapatellar Compression Bolt before inserting oblique screws.

Alternatively, attach the Impactor and Slap Hammer Shaft to use the backslap technique.



Locking screw in dynamic slot



Locking screw in compression mode

Backslap technique

STEP 12 PROXIMAL LOCKING SCREW INSERTION

Insert Trocar Assembly

Insert the three-part Trocar assembly (Soft Tissue Sleeve, Drill Sleeve, and Trocar) through the desired proximal hole in the Proximal Aiming Guide.

Ensure that the correct drill sleeve and Trocar combination are chosen for the corresponding nail.

Drill Size	Nail Diameter	Locking Screws
3.2mm	8 and 9mm Nails	4mm Locking Screws
4.2mm	10-15mm Nails	5mm Locking Screws

Drill and Determine Length

Ensure that the drill sleeve is securely placed. Use the drill corresponding to the screw size as shown in the table above. Drill through both cortices until the tip penetrates the far cortex.

Confirm drill bit position using fluoroscopy. Determine the length from the calibrated drill bit and select the corresponding locking screw. Remove the drill and drill sleeve. Alternatively, the depth gauge may be used to determine screw length.

Length calibration

Insert Locking Screw

Assemble the Locking Screw Driver by inserting the Retention Rod until it snaps into place.

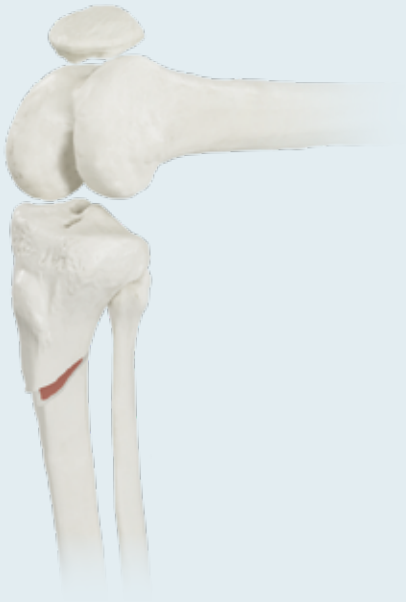
Select the appropriate locking screw. Using the Retention Rod, secure the locking screw to the Locking Screw Driver. Insert the locking screw through the Soft Tissue Sleeve, manually or under power.

Confirm placement using fluoroscopy.

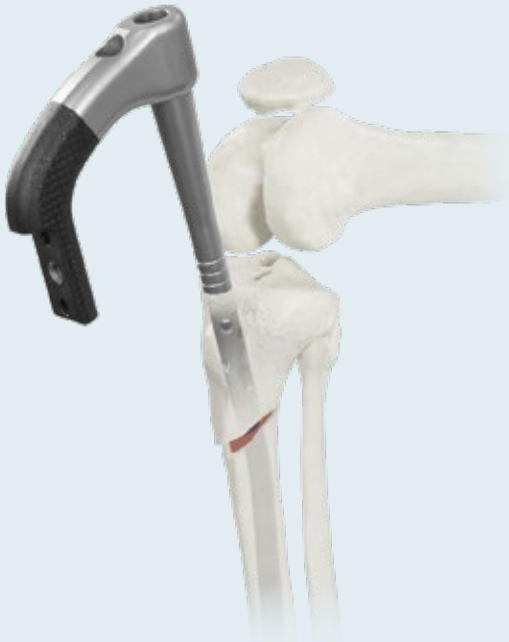
Repeat steps for additional proximal holes as necessary.

THREADED ANTERIOR OBLIQUE HOLE

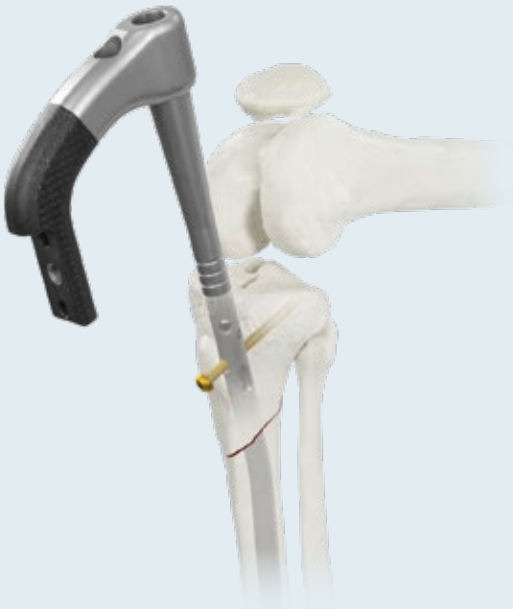
The threaded anterior oblique hole allows lagging through the nail to help reduce apex anterior deformity. The threaded feature in the nail is designed for fracture reduction.



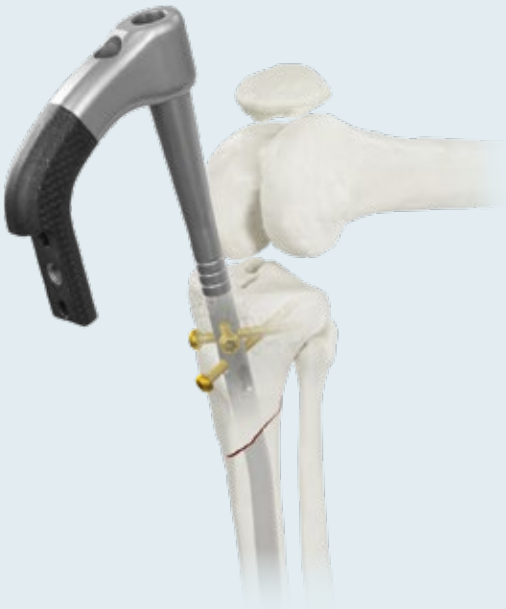
Proximal third fracture



Nail insertion



Fracture reduction



Final construct

HEADLESS LOCKING SCREWS

Headless screws are designed to decrease screw head prominence and reduce soft tissue irritation in the proximal and distal medial tibia.

Headless screws can be used instead of standard locking screws with any locking options in the AUTOBAHN™ Tibial Nailing System. They should only be placed in metaphyseal bone.

Headless Screw Insertion

Drill and determine length as described in Step 11.

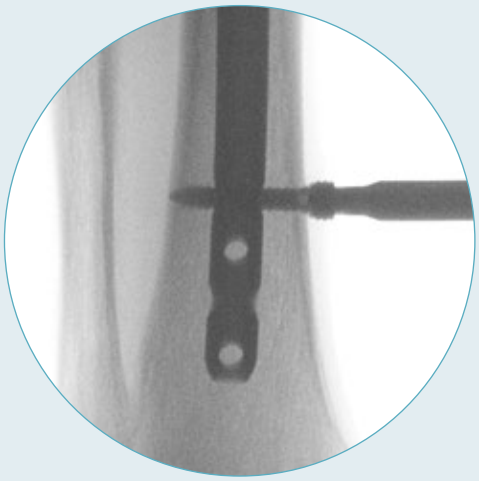
Attach the headless locking screw to the Locking Screw Driver using the self-retaining feature or the threaded capture mechanism.

Using fluoroscopy, insert the headless locking screw until the head of the screw is flush with the bone.

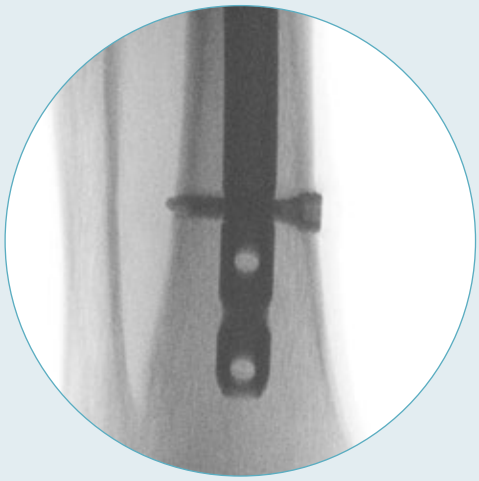
Verify screw length using fluoroscopy.

Repeat for additional proximal holes as necessary.

A countersink tool is available.



Headless Locking Screw insertion with driver



Headless Locking Screw fully inserted

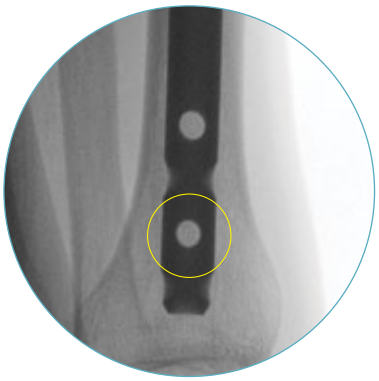
STEP 13 DISTAL LOCKING SCREW INSERTION

Alignment

Use the appropriate locking screws and drill bit for the selected diameter nail.

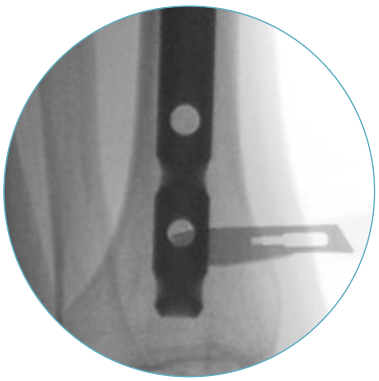
If using the backslap technique or Compression Bolt, distal locking must be performed before proximal locking.

Using fluoroscopy, confirm fracture reduction prior to distal locking. Align the C-arm with the distal hole until a perfect circle is formed.



Determine Incision Point

Determine the incision point using fluoroscopy.

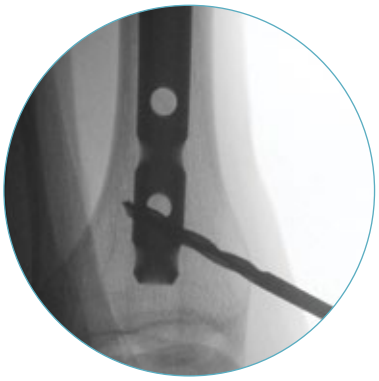


Drill and Determine Length

Insert the appropriate drill tip in the center of the locking hole. Confirm position using fluoroscopy. The drill should almost completely fill the hole. Hold the drill in this position and drill through both cortices.

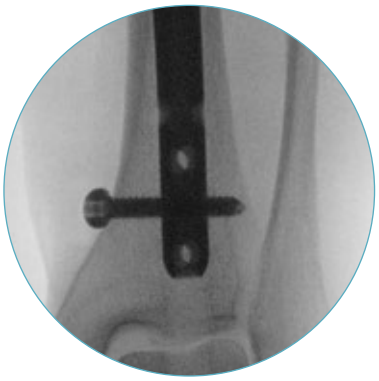
Remove the drill and insert the Locking Screw Length Gauge through the pre-drilled hole. Rest the gauge on the near cortical wall, extend the tip completely through the tibia, and retract until it reaches the far cortical wall.

Determine the screw length by reading the measurement on the gauge.



Insert Locking Screw

Insert the appropriate length locking screw using the Locking Screw Driver manually or under power. Verify screw length using fluoroscopy. Insert up to four locking screws following the steps above.



Removing Instruments

Loosen the Retention Bolt with the Retention Bolt Driver. Remove the Insertion Handle and Aiming Guide assembly together.

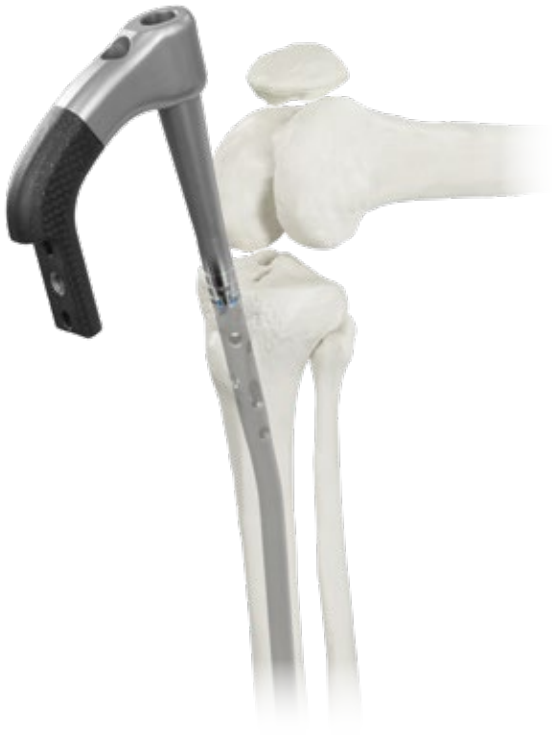
Detach the Aiming Guide by rotating the thumbwheel counterclockwise.

OPTIONAL: END CAP INSERTION

Once the nail is in position, remove the Insertion Handle by unthreading the Retention Bolt using the Retention Bolt Driver. Alternatively, remove the Retention Bolt as the Infrapatellar Insertion Handle can be used to align the end cap to the top of the nail.

Optional end caps are available to prevent bony ingrowth or to extend the nail length. The end cap engages the most proximal oblique locking screw to create a fixed-angle construct. Use a 1.8mm K-wire to assist with end cap insertion if desired. Attach the end cap to the Long Locking Screw Driver and insert into the top of the nail as desired. Confirm nail position using fluoroscopy.

End cap insertion



End cap fully inserted

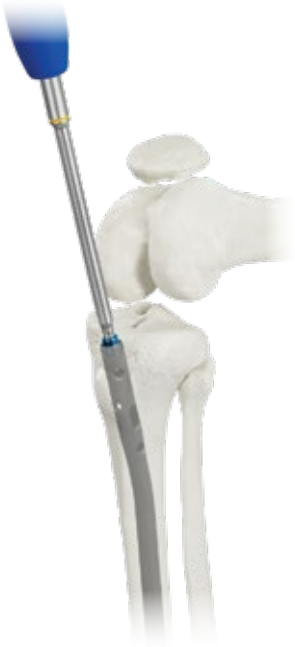
OPTIONAL: NAIL REMOVAL

Remove the nail through an infrapatellar incision.

Clear the end cap and the locking implants of any tissue ingrowth. Remove the end cap using the Locking Screw Driver. Remove all locking screws except one proximal locking screw using the Locking Screw Driver.

Before removing the final locking screw, thread the **Extraction Bolt** into the nail and tighten to prevent rotation or displacement of the nail posteriorly below the tibial plateau. Attach the Slap Hammer Shaft to the Extraction Screw. Remove the remaining locking screw using the Locking Screw Driver.

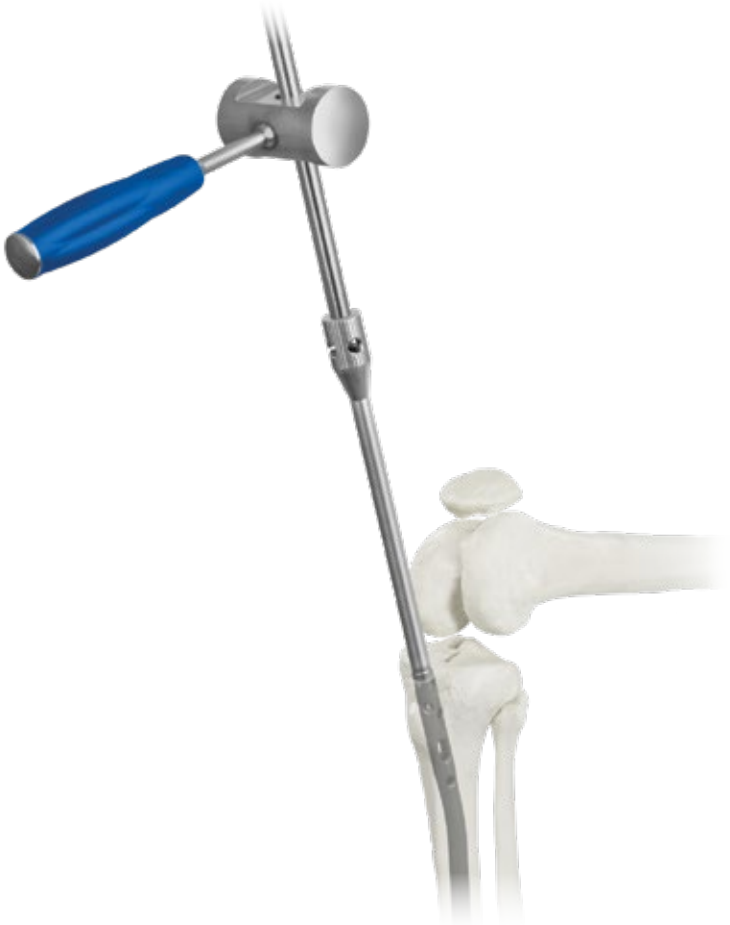
Gently impact to extract the nail using the Slotted Mallet.



End cap removal

Extraction Bolt inserted

Slap Hammer Shaft attachment



Nail removal

INSTRUMENT OVERVIEW

PROXIMAL ENTRY

Radiographic Length and Diameter Gauge 6183.1002

AUTOBAHN™ Tibial Nail Length Gauge 6183.1101

Extension Nail Length Gauge 6176.0011

Threaded Drill Point K-wire 3.2x450mm 6176.0021

12mm Cannulated Awl 6183.1004

12mm Infrapatellar Drill Sleeve 6183.1005

PROXIMAL ENTRY (CONT'D)

12mm Cannulated Entry Drill 6183.1006

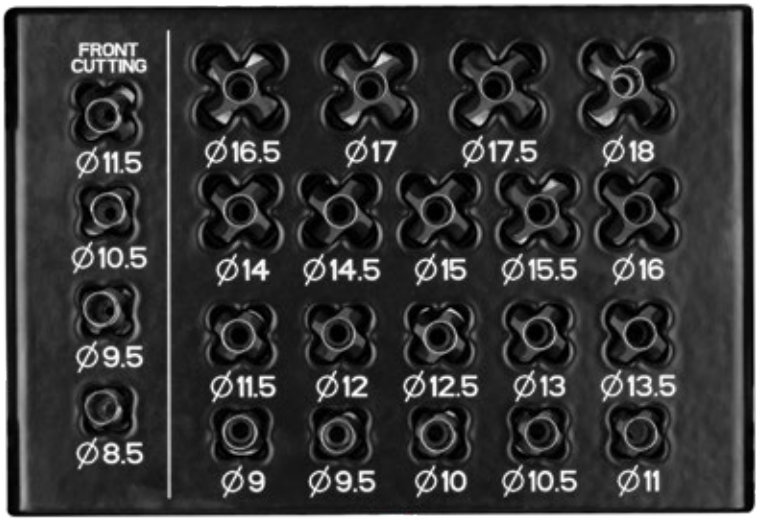
Suprapatellar Cannula Drill Sleeve 8mm-11mm 6183.1091

Suprapatellar Trocar 8mm-11mm 6183.1092

AUTOBAHN™ Tibial Nail Suprapatellar Cannula 8mm-11mm 6183.1096

Ball-Tip K-wire 3.0x1000mm 6176.0022

REAMING



Reamer Head Caddy 9182.0001

Flexible Reamer Shaft, 470mm 6182.0001

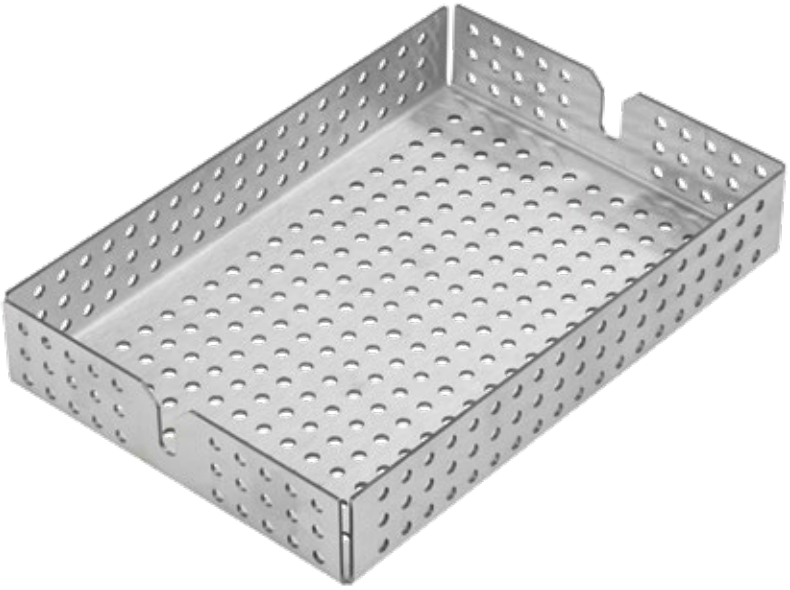
Flexible Reamer Shaft, 620mm 6182.0003

Reamer Extension Shaft 6182.0002

Front Cutting Reamer Heads, 8.5-11.5mm 6182.2085-.2115

Piloted Reamer Head, 9.0-18mm 6182.1090-.1180

REAMING (CONT'D)



Reamer Removal Tray 9182.0002

Cannulated T-Handle Jacobs Chuck 6173.9000

Intramedullary Reduction Device 6190.0080

REAMING (CONT'D)

Guide Wire Pusher 6176.0029

Exchange Tube 6183.1043

NAIL INSERTION

AUTOBAHN™ Tibial Nail Infrapatellar Handle Assembly 6183.1016

AUTOBAHN™ Tibial Nail Infrapatellar Retention Bolt 6183.1018

NAIL INSERTION (CONT'D)

AUTOBAHN™ Tibial Nail Suprapatellar Handle Assembly 6183.1015

AUTOBAHN™ Tibial Nail Suprapatellar Retention Bolt 6183.1017

8mm T-Handle Ratcheting Driver 6067.0020

NAIL INSERTION (CONT'D)

Retention Bolt Driver Shaft 6176.0027

8mm Self-Retaining Driver Shaft 6183.1102

Impactor 6183.1020

Slap Hammer Shaft 6183.1094

Slotted Mallet 6176.0020

LOCKING INSTRUMENTS

AUTOBAHN™ Tibial Nail Proximal Aiming Guide 6183.1024

Soft Tissue Drill Sleeve 6183.1054

Drill Sleeve 4.2mm 6183.1083

Trocar 4.2mm 6183.1085

4.2mm Drill, Short 150mm 6183.1030

4.2mm Drill Graduated, Long 330mm 6183.1031

LOCKING INSTRUMENTS (CONT'D)

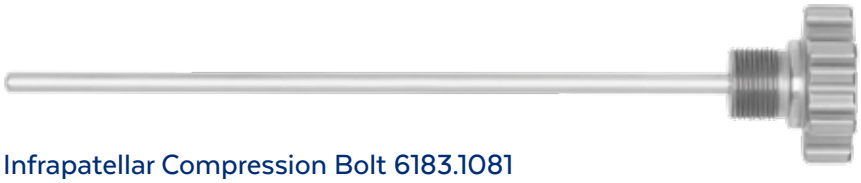
Drill Sleeve 3.3mm 6183.1084

Trocar 3.3mm 6183.1086

3.3mm Drill, Short 150mm 6183.1032

3.2mm Drill Graduated, Long 330mm 6183.1033

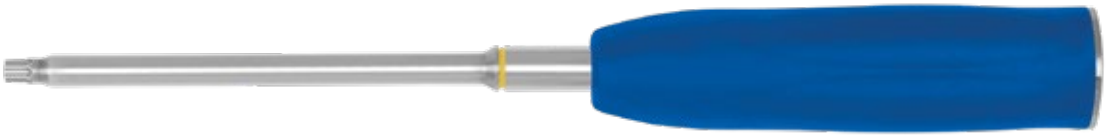
Suprapatellar Compression Bolt 6183.1087



Infrapatellar Compression Bolt 6183.1081

LOCKING INSTRUMENTS (CONT'D)

Retention Rod, Locking Screw, Short 6176.0061



Locking Screw Driver, Short 6176.0045

Retention Rod, Locking Screw, Short 6176.0063

Locking Screw Driver, Long 6176.0042

Retention Rod, Locking Screw, Short for Power 6176.0056

Locking Screw Driver, Short for Power 6176.0055

Retention Rod, Locking Screw, Long for Power 6176.0058

LOCKING INSTRUMENTS (CONT'D)

Locking Screw Driver, Long for Power 6176.0057

Length Gauge, Locking Screws 6176.0026

REMOVAL INSTRUMENTS

Locking Screw Removal Tool 6176.0031

4mm Locking Screw Removal Tool 6183.1103

Punch 6176.0032

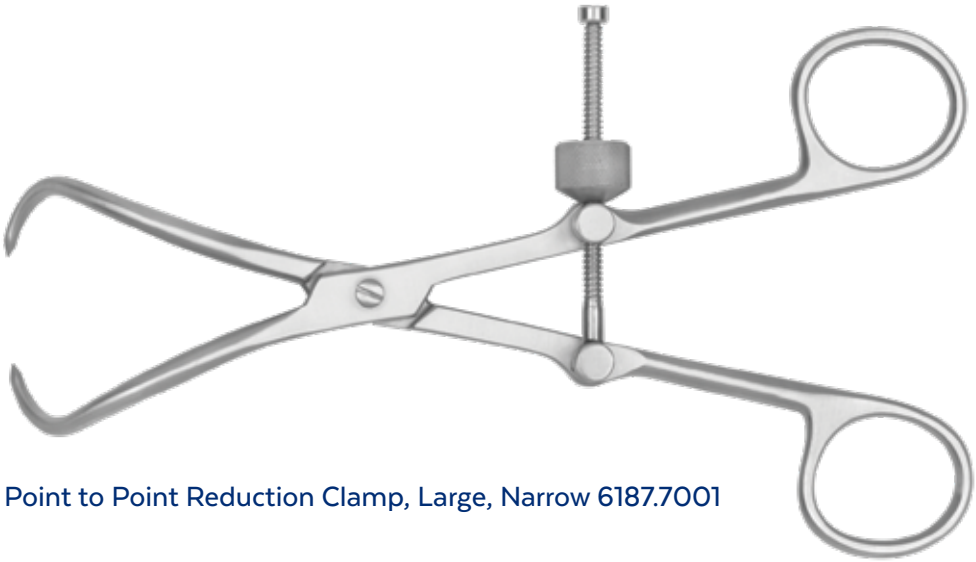
Trephine 6176.0048

REMOVAL INSTRUMENTS (CONT'D)

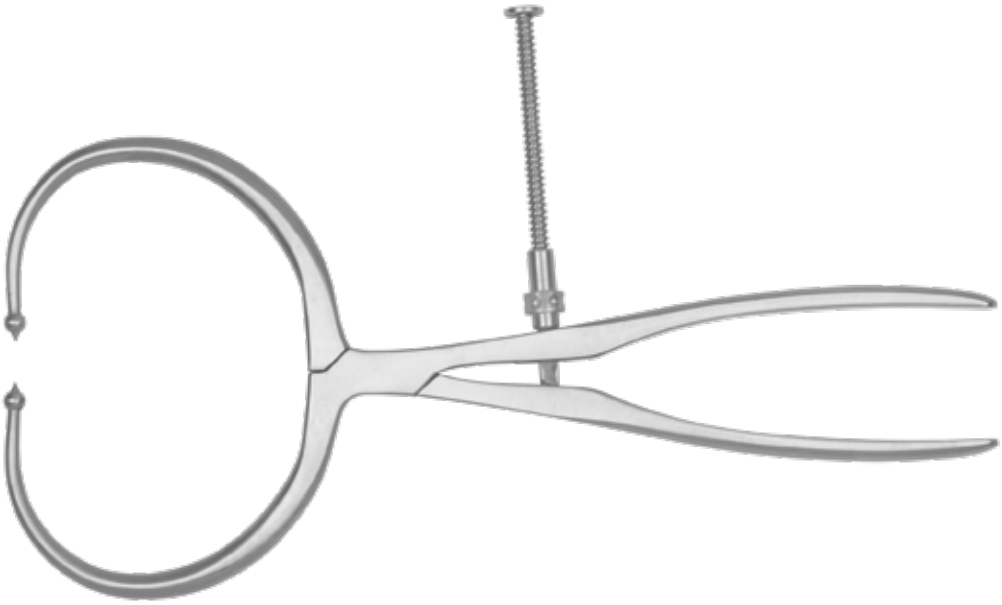
AUTOBAHN™ Tibial Nail Extraction Bolt 6183.1001

Extractor Pin Wrench 6176.0066

REDUCTION INSTRUMENTS



Point to Point Reduction Clamp, Large, Narrow 6187.7001



Ball Spike Reduction Clamp, Large 6187.7004

REDUCTION INSTRUMENTS (CONT'D)

Ball Spike Pusher 6183.1098

SMALL FRAGMENT INSTRUMENTS

T15 Driver, SR, Cannulated, 150mm AO Quick Connect 6168.5215

Screw Holding Forceps 6179.2000

3.5mm Spring Loaded Soft Tissue Protector 6179.3135

Cannulated Quick Connect Handle, Internal Coupling 6188.7000

AUTOBAHN™ Tibial Nailing System
IMPLANTS 9183.0000

Nails

Length	8mm	9mm	10mm
225-435mm	1183.1822S - 1183.1843S	1183.1922S - 1183.1943S	1183.1022S - 1183.1043S

Length	11mm	12mm
225-435mm	1183.1122S - 1183.1143S	1183.1222S - 1183.1243S

Locking Screws

Length	4mm Fully Threaded	4mm Partially Threaded
20-130mm	1183.4020S - 1183.4130S	1183.6020S - 1183.6130S

Length	5mm Fully Threaded	5mm Partially Threaded
20-130mm	1183.5020S - 1183.5130S	1183.7020S - 1183.7130S

Headless Locking Screws

Length	4mm Fully Threaded	4mm Partially Threaded
20-130mm	1183.8020S - 1183.8130S	1183.0020S - 1183.0130S

Length	5mm Fully Threaded	5mm Partially Threaded
20-130mm	1183.2020S - 1183.2130S	1183.3020S - 1183.3130S

End Caps

PART NO.	DESCRIPTION
1183.9800S - 1183.9820S	0-20mm

Set Screw

PART NO.	DESCRIPTION
1183.9010S	Set Screw

K-wires

PART NO.	DESCRIPTION
6176.0021S	3.2x450mm Threaded
6176.0022S	3.0x1000mm Ball Tip

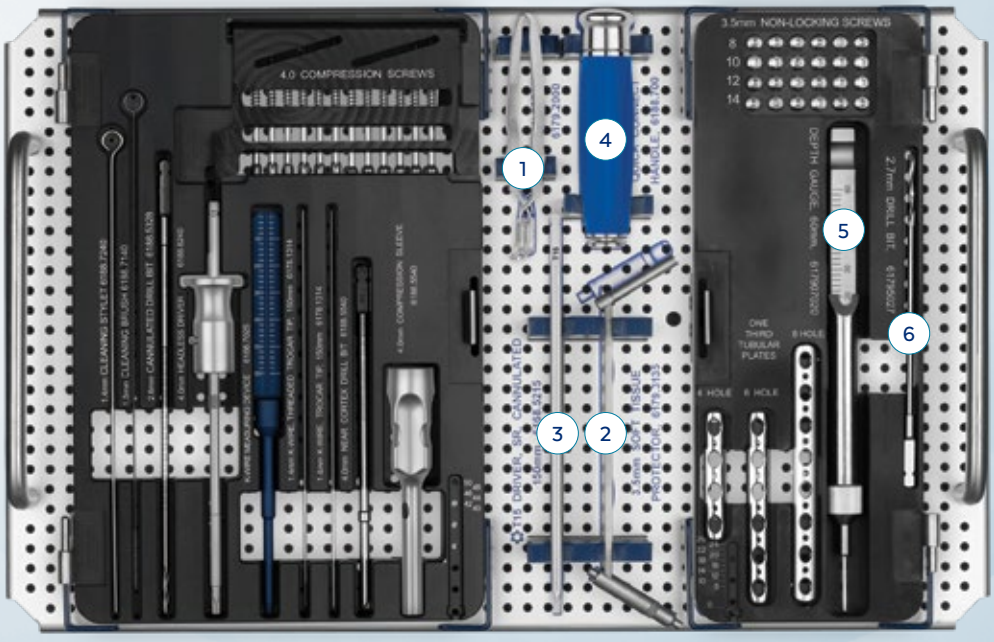
ANTHEM® Small Fragment Fracture System
MODULE 9183.0004

Small Fragment Implants

PART NO.	DESCRIPTION
2179.1324	ANTHEM® SS One Third Tubular Plate, non-locking, 4 hole, 48mm
2179.1326	ANTHEM® SS One Third Tubular Plate, non-locking, 6 hole, 72mm
2179.1328	ANTHEM® SS One Third Tubular Plate, non-locking, 8 hole, 96mm
2179.3008	SS Non-Locking Screw, 3.5x8mm
2179.3010	SS Non-Locking Screw, 3.5x10mm
2179.3012	SS Non-Locking Screw, 3.5x12mm
2179.3014	SS Non-Locking Screw, 3.5x14mm

Small Fragment Instruments

	PART NO.	DESCRIPTION
1	6179.2000	Screw Holding Forceps
2	6179.3135	3.5mm Spring Loaded Soft Tissue Protector
3	6168.5215	T15 Driver, SR, Cannulated, 150mm, AO Quick Connect
4	6188.7000	Cannulated Quick Connect Handle, Internal Coupling
5	6179.7020	Depth Gauge, 60mm
6	6179.5027	2.7mm Drill Bit, 125mm, AO Quick Connect
	9183.0004	AUTOBAHN™ Tibial Nailing System Small Fragment Module



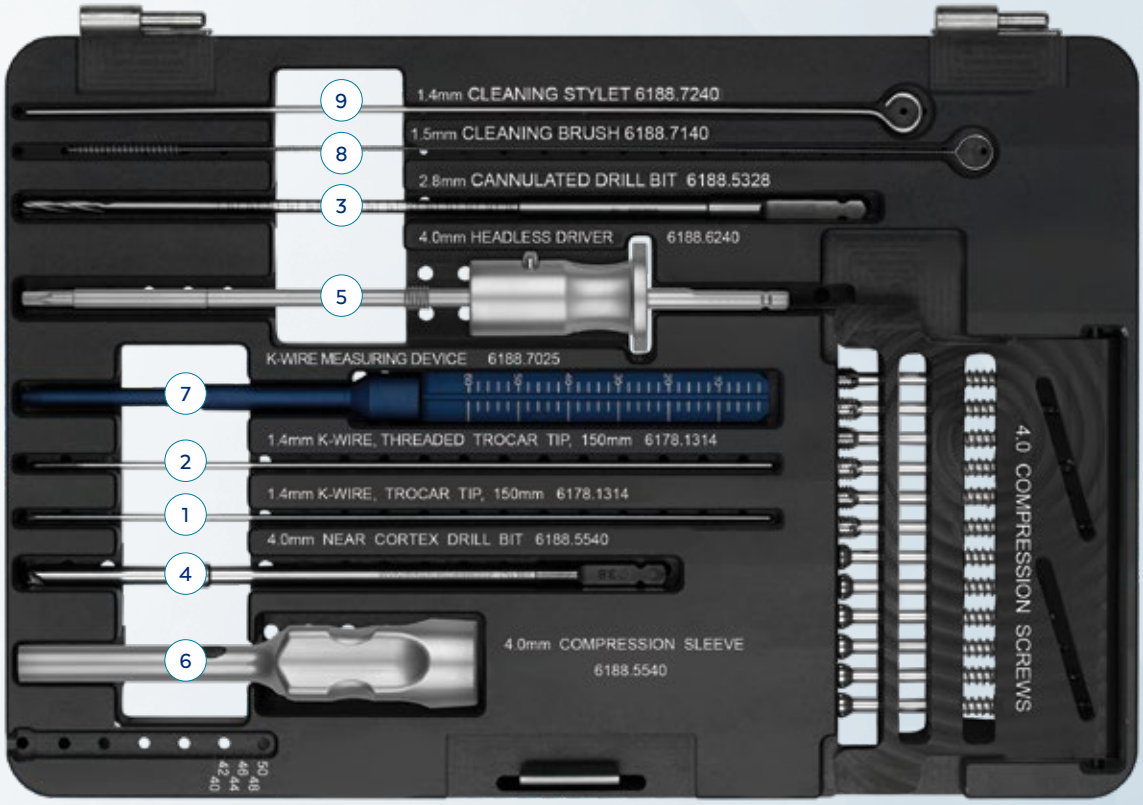
CAPTIVATE™ 4.0 Headless Compression Screw
MODULE 9183.0005

CAPTIVATE™ 4.0mm Headless Compression Screws

PART NO.	DESCRIPTION
1178.4232	CAPTIVATE™ Ti 4.0x32mm Cannulated Screw, Short Thread
1178.4234	CAPTIVATE™ Ti 4.0x34mm Cannulated Screw, Short Thread
1178.4236	CAPTIVATE™ Ti 4.0x36mm Cannulated Screw, Short Thread
1178.4238	CAPTIVATE™ Ti 4.0x38mm Cannulated Screw, Short Thread
1178.4240	CAPTIVATE™ Ti 4.0x40mm Cannulated Screw, Short Thread
1178.4242	CAPTIVATE™ Ti 4.0x42mm Cannulated Screw, Short Thread
1178.4244	CAPTIVATE™ Ti 4.0x44mm Cannulated Screw, Short Thread
1178.4246	CAPTIVATE™ Ti 4.0x46mm Cannulated Screw, Short Thread
1178.4248	CAPTIVATE™ Ti 4.0x48mm Cannulated Screw, Short Thread
1188.4232	CAPTIVATE™ Ti 4.0x32mm Headless Cannulated Screw, Short Thread
1188.4234	CAPTIVATE™ Ti 4.0x34mm Headless Cannulated Screw, Short Thread
1188.4236	CAPTIVATE™ Ti 4.0x36mm Headless Cannulated Screw, Short Thread
1188.4238	CAPTIVATE™ Ti 4.0x38mm Headless Cannulated Screw, Short Thread
1188.4240	CAPTIVATE™ Ti 4.0x40mm Headless Cannulated Screw, Short Thread
1188.4242	CAPTIVATE™ Ti 4.0x42mm Headless Cannulated Screw, Short Thread
1188.4244	CAPTIVATE™ Ti 4.0x44mm Headless Cannulated Screw, Short Thread
1188.4246	CAPTIVATE™ Ti 4.0x46mm Headless Cannulated Screw, Short Thread
1188.4248	CAPTIVATE™ Ti 4.0x48mm Headless Cannulated Screw, Short Thread

CAPTIVATE™ 4.0mm Compression Screw Instruments

	PART NO.	DESCRIPTION
1	6178.1114	1.4mm K-Wire, Trocar Tip, 150mm
2	6178.1314	1.4mm K-Wire, Threaded Trocar Tip, 150mm
3	6188.5328	2.8mm Drill Bit, 170mm, 1.5mm Cannulation
4	6188.5540	4.0mm Near Cortex Drill Bit, 1.5mm Cannulation
5	6188.6240	4.0mm Headless Driver
6	6188.6740	4.0mm Headless Compression Sleeve
7	6188.7025	1.5mm K-Wire Measuring Device
8	6188.7140	1.6mm Cleaning Brush, 185mm
9	6188.7240	1.4mm Cleaning Stylet, 180mm
	9183.0005	AUTOBAHN™ Tibial Nailing System Compression Screw Module


9
1.4mm CLEANING STYLET 6188.7240
8
1.5mm CLEANING BRUSH 6188.7140
3
2.8mm CANNULATED DRILL BIT 6188.5328
4.0mm HEADLESS DRIVER 6188.6240
5
K-WIRE MEASURING DEVICE 6188.7025
7
1.4mm K-WIRE, THREADED TROCAR TIP, 150mm 6178.1314
2
1.4mm K-WIRE, TROCAR TIP, 150mm 6178.1314
1
4.0mm NEAR CORTEX DRILL BIT 6188.5540
4
4.0mm COMPRESSION SLEEVE
6188.5540
6
4.0 COMPRESSION SCREWS
40 42 44 46 48 50

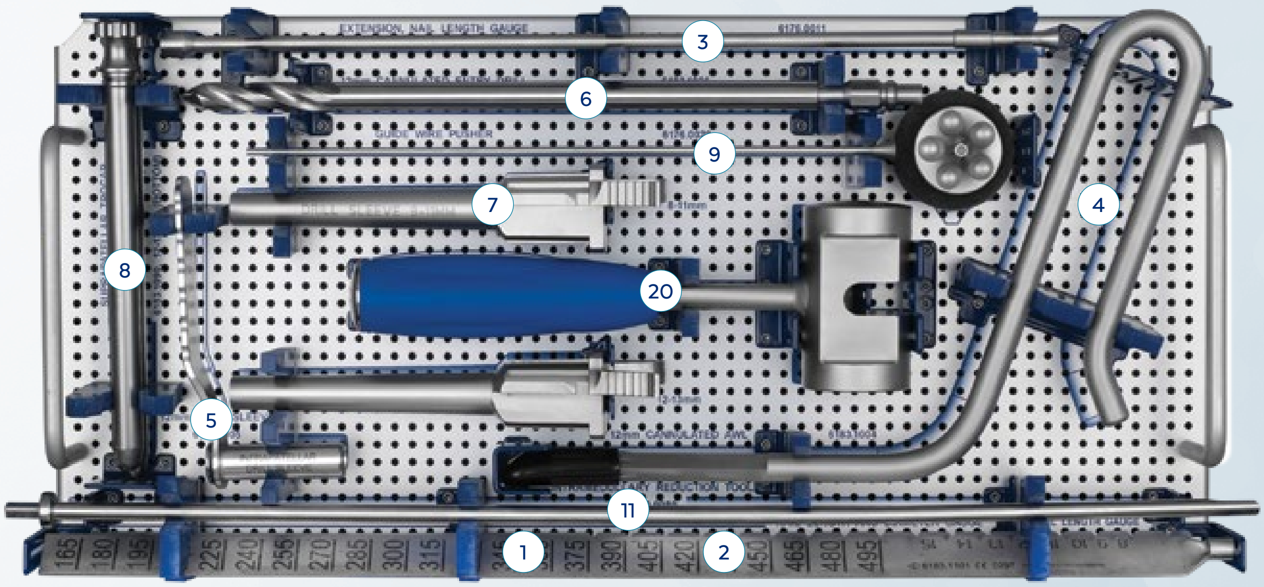
AUTOBAHN™ Tibial Nailing System
INSTRUMENTS 9183.0001

Proximal Entry Instruments

	PART NO.	DESCRIPTION	QTY
1	6183.1002	Radiographic Length and Diameter Gauge	1
2	6183.1101	AUTOBAHN™ Tibial Nail Length Gauge	1
3	6176.0011	Extension Nail Length Gauge	1
4	6183.1004	12mm Cannulated Awl	1
5	6183.1005	12mm Infrapatellar Drill Sleeve	1
6	6183.1006	12mm Cannulated Entry Drill	1
7	6183.1091	Suprapatellar Drill Sleeve 8-11mm	1
8	6183.1092	Suprapatellar Trocar 8-11mm	1
9	6176.0029	Guide Wire Pusher	1
10	6173.9000	T-Handle 3 Jaw Chuck	1
11	6190.0080	Intramedullary Reduction Device	1

Nail Insertion Instruments

	PART NO.	DESCRIPTION	QTY
12	6183.1015	AUTOBAHN™ Tibial Nail Suprapatellar Handle	1
13	6183.1016	AUTOBAHN™ Tibial Nail Infrapatellar Handle	1
14	6183.1017	AUTOBAHN™ Tibial Nail Suprapatellar Retention Bolt	2
15	6183.1018	AUTOBAHN™ Tibial Nail Infrapatellar Retention Bolt	2
16	6067.0020	T-Handle, Ratcheting, 1/4” Quick Connect	1
17	6173.0027	Retention Bolt Driver	1
18	6183.1102	8mm Self-Retaining Driver Shaft	1
19	6183.1020	Impactor	1
20	6176.0020	Slotted Mallet	1
21	6183.1087	Suprapatellar Compression Bolt	1
22	6183.1081	Infrapatellar Compression Bolt	1
23	6183.1094	Slap Hammer Shaft	1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GUIDE WIRE PUSHER
12mm CANNULATED AWL
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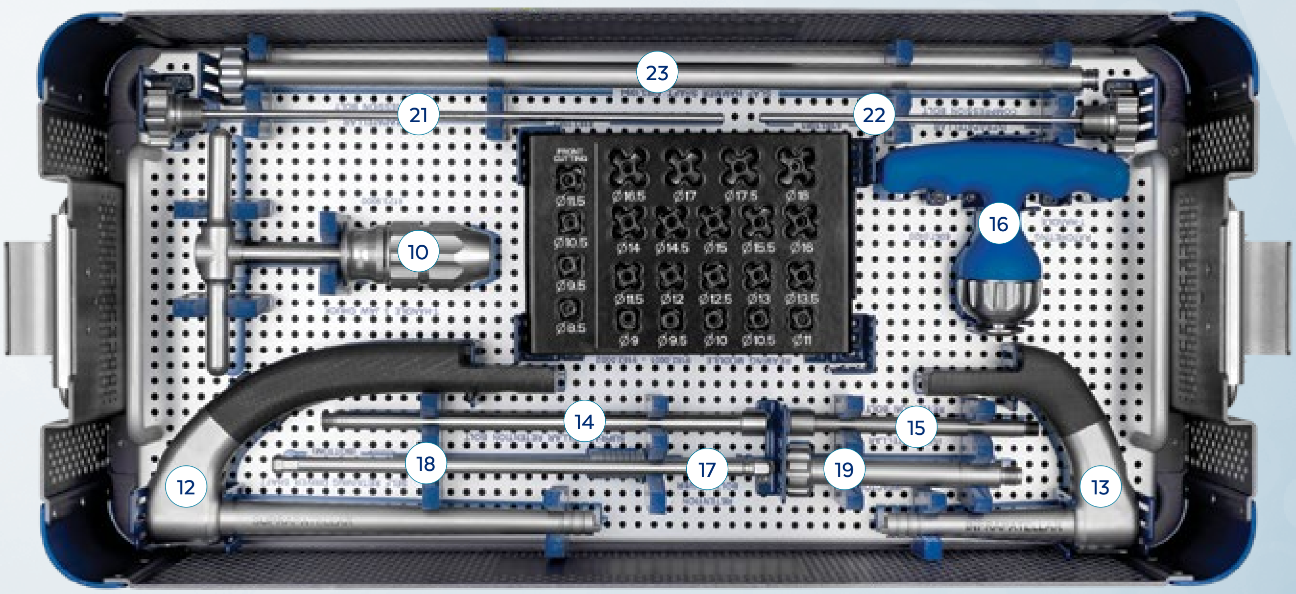
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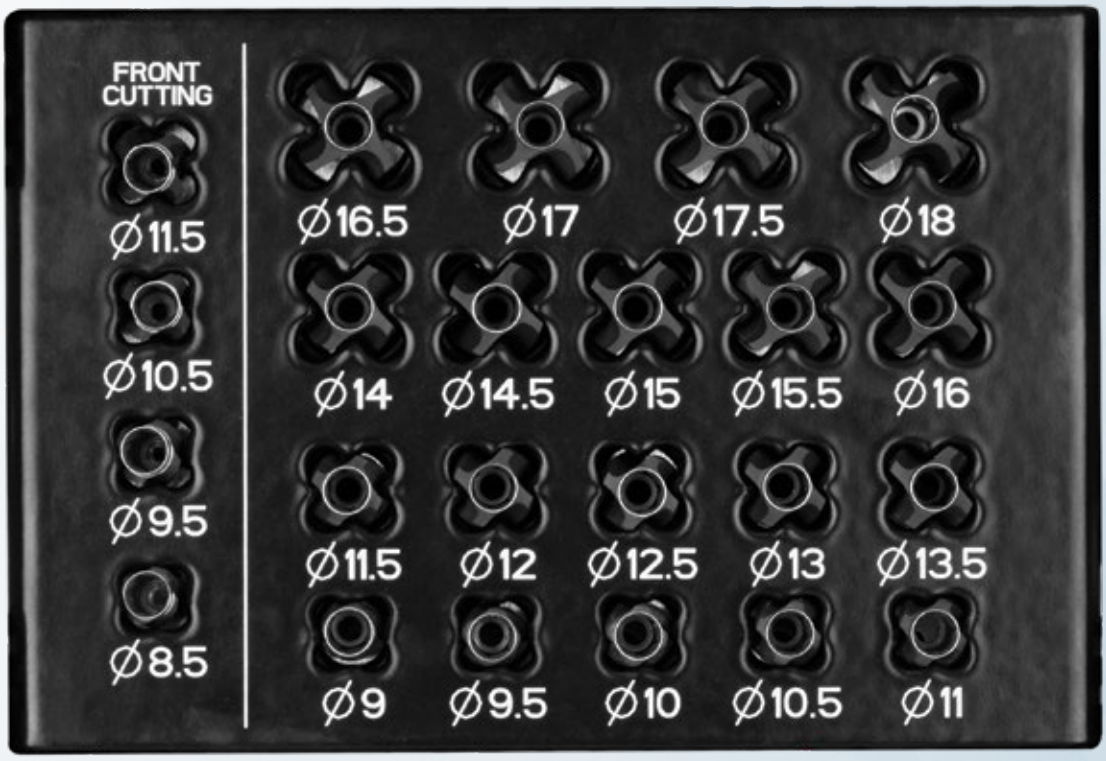
UNIVERSAL REAMER
MODULE 9182.0001

Reaming Instruments

PART NO.	DESCRIPTION	QTY
6182.2085	Front Cutting Reamer Head, 8.5mm	1
6182.2095	Front Cutting Reamer Head, 9.5mm	1
6182.2105	Front Cutting Reamer Head, 10.5mm	1
6182.2115	Front Cutting Reamer Head, 11.5mm	1
6182.1090	Piloted Reamer Head, 9mm	1
6182.1095	Piloted Reamer Head, 9.5mm	1
6182.1100	Piloted Reamer Head, 10mm	1
6182.1105	Piloted Reamer Head, 10.5mm	1
6182.1110	Piloted Reamer Head, 11mm	1
6182.1115	Piloted Reamer Head, 11.5mm	1
6182.1120	Piloted Reamer Head, 12mm	1
6182.1125	Piloted Reamer Head, 12.5mm	1
6182.1130	Piloted Reamer Head, 13mm	1
6182.1135	Piloted Reamer Head, 13.5mm	1
6182.1140	Piloted Reamer Head, 14mm	1
6182.1145	Piloted Reamer Head, 14.5mm	1
6182.1150	Piloted Reamer Head, 15mm	1
6182.1155	Piloted Reamer Head, 15.5mm	1
6182.1160	Piloted Reamer Head, 16mm	1
6182.1165	Piloted Reamer Head, 16.5mm	1
6182.1170	Piloted Reamer Head, 17mm	1
6182.1175	Piloted Reamer Head, 17.5mm	1
6182.1180	Piloted Reamer Head, 18mm	1
6182.0002	Reamer Removal Tray	1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AUTOBAHN™ Tibial Nailing System
INSTRUMENTS 9183.0002

Locking Instruments

	PART NO.	DESCRIPTION	QTY
1	6183.1024	AUOTBAHN™ Tibial Nail Proximal Aiming Guide	1
2	6183.1083	Drill Sleeve 4.2	1
3	6183.1084	Drill Sleeve 3.2	1
4	6183.1085	Trocar 4.2	1
5	6183.1086	Trocar 3.2	1
6	6183.1030	4.2 Drill Graduated, Long 330mm	2
7	6183.1031	4.2 Drill, Short 150mm	2
8	6183.1032	3.2 Drill Graduated, Long 330mm	2
9	6183.1033	3.2 Drill, Short 150mm	2
10	6176.0045	Locking Screw Driver, Short	1
11	6176.0042	Locking Screw Driver, Long	1
12	6183.1054	Soft Tissue Drill Sleeve	2
13	6176.0026	Length Gauge, Locking Screws	1
14	6176.0055	Locking Screw Driver, Short, for Power	1
15	6176.0056	Retention Rod, Locking Screw, Short for Power	1
16	6176.0057	Locking Screw Driver, Long, for Power	1
17	6176.0058	Retention Rod, Locking Screw, Long for Power	1
18	6176.0061	Retention Rod, Locking Screw, Short	1
19	6176.0063	Retention Rod, Locking Screw, Long	1

Reduction Instruments

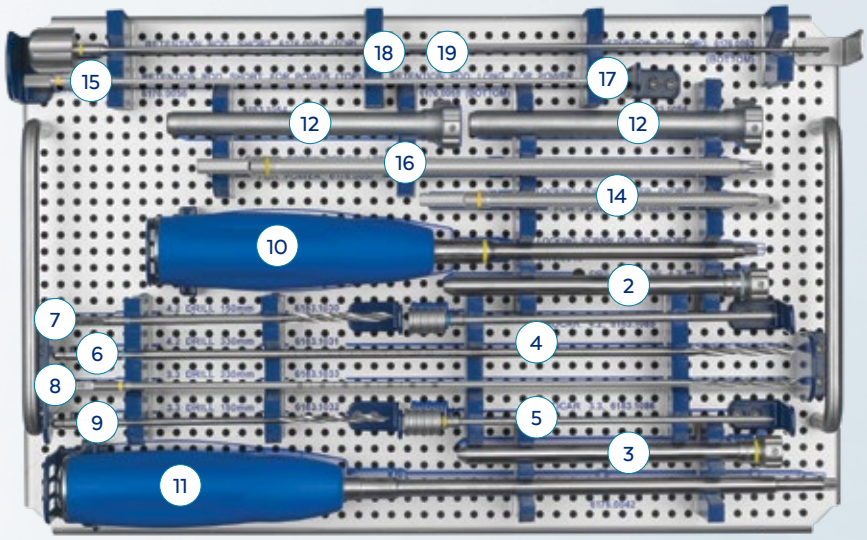
	PART NO.	DESCRIPTION	QTY
20	6183.1098	Ball Spike Pusher Reduction Instrument	1
21	6187.7001	Point to Point Reduction Clamp, Large, Narrow	1
22	6187.7004	Ball Spike Reduction Clamp, Large	1

Removal Instruments

	PART NO.	DESCRIPTION	QTY
23	6183.1001	AUTOBAHN™ Tibial Nail Extraction Bolt	1
24	6183.1103	4mm Locking Screw Removal Tool	1
25	6176.0031	Locking Screw Removal Tool	1
26	6176.0032	Punch	1
27	6176.0048	Trephine	1

Sterile Packed Instruments

PART NO.	DESCRIPTION	QTY
6716.0021S	3.2 x 450mm K-wires	6
6176.0022S	3.0x1000mm Ball Tip	2
6183.1096S	Suprapatellar Cannula (8-10mm)	2
6183.1043S	Exchange Tube	1
6182.0001S	Flexible Reamer Shaft, 470mm	2
6182.0003S	Flexible Reamer Shaft, 620mm	2
6182.0002S	Reamer Extension	2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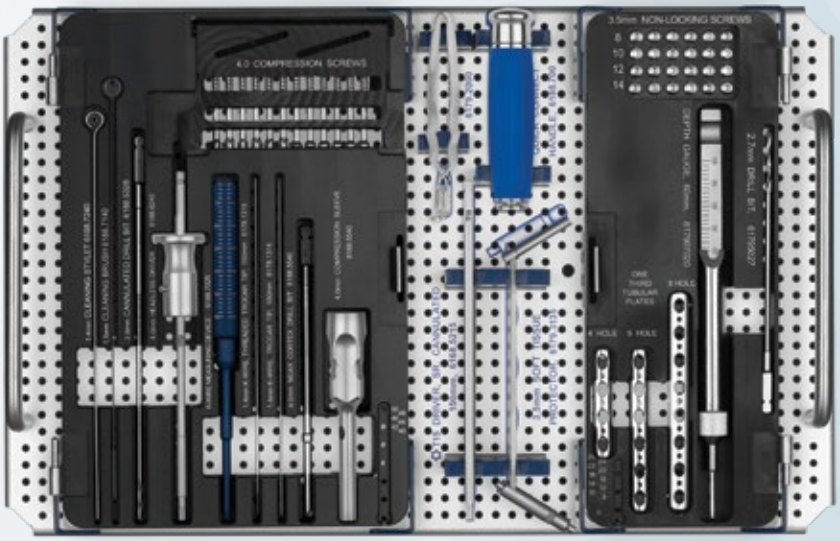
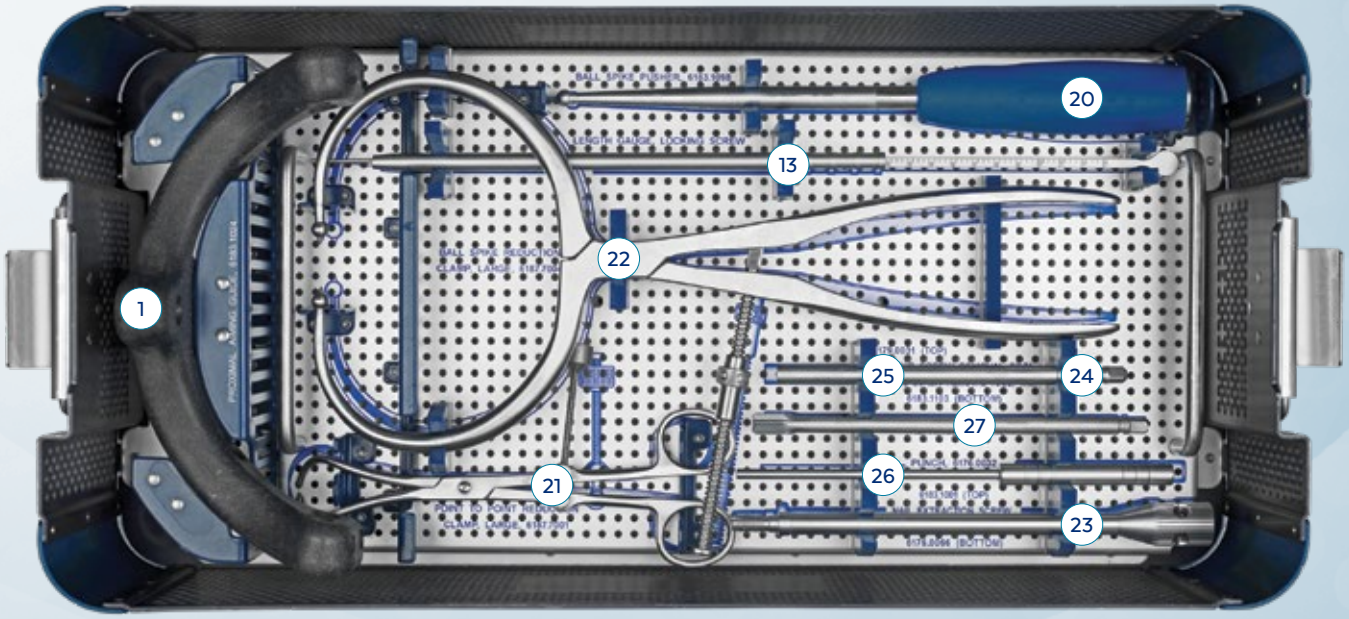

4.0 COMPRESSION SCREWS
3.5mm NON-LOCKING SCREWS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IMPORTANT INFORMATION ON ON THE AUTOBAHN™ NAILING SYSTEM

DESCRIPTION

The AUTOBAHN™ Nailing System is a family of intramedullary nails and screws designed to be used for internal bone fixation. The implants are available in various lengths and diameters to accommodate a wide range of patient anatomy. The nails are secured with locking screws and all devices are manufactured from titanium alloy, cobalt chromium molybdenum alloy, or titanium molybdenum alloy, and may include radiolucent PEEK polymer inserts.

INDICATIONS

The AUTOBAHN™ Tibial Nail is indicated for stabilization of fractures in skeletally mature patients, specifically fractures of the proximal and distal tibia and the tibial shaft, open and closed tibial shaft fractures, certain pre- and postisthmic fractures, non-unions, malunions, pseudarthrosis, corrective osteotomies, prophylactic nailing of impending pathological fractures, tumor resections, simple long bone fractures, severely comminuted, spiral, large oblique and segmental fractures, polytrauma and multiple fractures, reconstruction, following tumor resection and grafting, supracondylar fractures, and bone lengthening and shortening.

The AUTOBAHN™ Trochanteric Nail is indicated for treatment of fractures in adults and adolescents (12-21 years of age) in which the growth plates have fused for the following indications: basal neck fractures, fixation of stable and unstable intertrochanteric, pertrochanteric, and subtrochanteric fractures, pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions, combinations of pertrochanteric, intertrochanteric, basal neck fractures, long subtrochanteric fractures, tumor resections, fractures resulting from trauma, nonunions, malunions, and revision procedures.

AUTOBAHN™ Antegrade/Retrograde Femoral Nails are indicated for long bone fracture fixation in skeletally mature patients, specifically femoral fracture fixation, which may include the following: open and closed femoral fractures, pseudoarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, tumor resections, supracondylar fractures, including those with intra-articular extension, ipsilateral hip/shaft fractures, ipsilateral femur/tibia fractures, fractures proximal to a total knee arthroplasty, fractures distal to hip joint, nonunions and malunions, poly trauma patients, fractures in the morbidly obese, fractures involving osteopenic and osteoporotic bone, compound and simple shaft fractures, proximal, metaphyseal, and distal shaft fractures, segmental fractures, closed supracondylar fractures, fractures involving femoral condyles, comminuted fractures, fractures with bone loss, and periprosthetic fractures.

WARNINGS

The correct implant selection is extremely important. Failure to use the appropriate implant for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the implant and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.

PRECAUTIONS

The implantation of intramedullary nail devices should be performed only by experienced surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Surgical implants must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

MRI SAFETY INFORMATION

These devices have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CONTRAINDICATIONS

Use of these implants is contraindicated in patients with the following conditions:

- Any active or suspended latent infection or marked local inflammation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- A medullary canal obliterated by a previous fracture or tumor.
- Skeletally immature patients.
- Material sensitivity, documented or suspected.
- Patients having inadequate tissue coverage over the operative site.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

ADVERSE EFFECTS

In many instances, adverse results may be clinically related rather than device related. The following are the most frequent adverse effects involving the use of internal fracture fixation devices:

- Delayed union or non-union of the fracture site.
- These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. Internal fixation devices are load sharing devices which are intended to hold fracture bone surface in a position to facilitate healing. If healing is delayed or does not occur, the appliance may eventually break due to metal fatigue. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.
- Conditions attributable to non-union, osteoporosis, osteomalicia, diabetes, inhibited revascularization and poor bone formation can cause loosening, bending, cracking, fracture of the device or premature loss of rigid fixation with the bone.
- Improper alignment can cause a malunion of the bone and/or bending, cracking or even breakage of the device.
- Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
- Early or late infection, deep or superficial.
- Deep venous thrombosis.
- Avascular necrosis.
- Shortening of the effected bone/fracture site.
- Subclinical nerve damage may possibly occur as a result of the surgical trauma.
- Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.
- Fat embolism or adult respiratory distress from reaming the medullary canal.

CAUTIONS

Pre-operative

- Implants are single use only.
- Implants that came in contact with body fluids should never be reused.
- Ensure that all components needed for surgery are available in the surgical suite.
- Inspection is recommended prior to surgery to determine if implants have been damaged during storage.
- While rare, intra-operative fracture or breakage of instruments can occur. Instruments which have experienced excessive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage prior to surgery.

Intra-operative

- Avoid surface damage of implants.
- Discard all damaged or mishandled implants
- Contouring or bending of an implant should be avoided where possible, because it may reduce its fatigue strength and can cause failure under load.
- Implants are available in different versions, varying for example in length, diameter, material and number of drilled holes. Select the required version carefully.
- During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, is secure.
- Implants which consist of several components must only be used in the prescribed combination (refer to the AUTOBAHN™ Surgical Technique Guide).

IMPORTANT INFORMATION ON ON THE AUTOBAHN™ NAILING SYSTEM

- After the procedure check the proper positioning of all implants using fluoroscopy.
- Do not use components from this system in conjunction with components from any other manufacturer's system unless otherwise specified (refer to the AUTOBAHN™ Surgical Technique Guide).

Post-operative

- Post-operative patient activity: These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason post-operative instructions and warnings to patients are extremely important. External immobilization (e.g. bracing or casting) may be employed until X-rays or other procedures confirm adequate bone consolidation.
- The injured limb should be kept elevated.
- For stable fracture that are locked statically or dynamically, full weight bearing walking may be started immediately.
- In the event of a delay in bone consolidation, or if such consolidation does not take place, or if explantation is not carried out, complications may occur, for example fracture or loosening of the implant or instability of the implant system. Regular post-operative examinations (e.g., X-ray checks) are advisable.
- If patients cannot follow the recommendations of the physician because of any mental or neuromuscular disorder. For this reason those patients must have additional post-operative follow-up.
- Implant removal should be followed by adequate postoperative management to avoid fracture or refracture of the bone.

Informing the Patient

The implant affects the patient's ability to carry loads and her/his mobility and general living circumstances. The surgeon must counsel each patient individually on correct behavior and activity after the implantation.

The surgeon must warn patient that the device cannot and does not replicate a normally healthy bone, that the device can break or become damaged as a result of strenuous activity, trauma, malunion or non-union and that the device has a finite expected service life and may need to be removed at some time in the future.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

These implants and instruments may also be provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery.

Implants and sterile-packed instruments are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

CLEANING

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed tray. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated following ISO 17665-1:2006 Sterilization of health care products – Moist heat to ensure an SAL of 10-6. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

IMPORTANT INFORMATION ON ON THE AUTOBAHN™ NAILING SYSTEM

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY	℞ ONLY	PRESCRIPTION USE ONLY

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CE 0297

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